FEDERAL TRADE COMMISSION

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FEDERAL TRADE COMMISSION

In the Matter of:	)
SCHERING-PLOUGH CORPORATION,	)
a corporation,	)
and	)
UPSHER-SMITH LABORATORIES,	) File No. D09297
a corporation,	)
and	)
AMERICAN HOME PRODUCTS,	)
a corporation.	)
----------	)

Tuesday, March 5, 2002

10:30 a.m.

TRIAL VOLUME 26

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

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P R O C E E D I N G S

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JUDGE CHAPPELL: Good morning, everyone.

ALL COUNSEL: Good morning, Your Honor.

JUDGE CHAPPELL: Let's reconvene docket 9297. What do we have?

MR. CURRAN: Your Honor, Upsher-Smith is prepared to call our next witness, and that's Dr. William Kerr, an economist, and my colleague, Mr. Gidley, will handle this witness.

JUDGE CHAPPELL: Okay.

MS. BOKAT: Your Honor, just a reminder, we have our rebuttal witness, Dr. Banakar, going on this afternoon. Remember, we addressed this last week. We had an agreement that Dr. Banakar could go on this afternoon because tomorrow morning he's leaving the country for a month.

JUDGE CHAPPELL: And we will go until he's finished, right?

MS. BOKAT: Right.

JUDGE CHAPPELL: So, everyone can plan their caffeine intake accordingly.

MS. BOKAT: Yeah, the arrangement we have was that Dr. Banakar could go on after the lunch break, even if it meant splitting a witness. Now, apparently

that has changed. Upsher-Smith seems to be indicating that they're not willing to break Dr. Kerr's testimony.

JUDGE CHAPPELL: What do you mean, they seem to be? Don't you know?

MS. BOKAT: That was what they represented to me this morning, Your Honor.

JUDGE CHAPPELL: Okay.

MR. GIDLEY: Yes, Your Honor, that is what I represented to Ms. Bokat. We had agreed or offered that their rebuttal case could start with Banakar first thing this morning, put Banakar on and off, and then call Kerr, or alternatively, do Kerr all the way and then start Banakar, and that's not agreeable to complaint counsel. They want to chop up Kerr, and we at this late stage in the proceedings would prefer that Dr. Kerr be on and off the witness stand, and it's probably easier for everyone to do it that way.

JUDGE CHAPPELL: And Banakar, he's rebutting what just generally? I don't need to know everything.

MS. BOKAT: He's a patent-related expert witness on the technical side. He's not a lawyer. He's a technical person who will be rebutting the testimony heard from Dean Banker and Mr. Langer -- Dr. Langer.

JUDGE CHAPPELL: And not Kerr?

MS. BOKAT: No, I believe Mr. Kerr -- Dr. Kerr is an economist.

JUDGE CHAPPELL: Okay, then why don't we start with Banakar?

MS. BOKAT: He would be prepared to go on at 12:00 today, Your Honor.

JUDGE CHAPPELL: Okay. And you're anticipating direct of -- is it Dr. Kerr?

MR. GIDLEY: Yes, Your Honor.

JUDGE CHAPPELL: How long?

MR. GIDLEY: It's hard to say. I don't know the exact time. Two, two and a half, three hours. I'm going to try to move it along.

JUDGE CHAPPELL: And unfortunately, we couldn't start at 9:30, because when we go after 7:00, the court reporters need time to -- Susanne is great, but she's only human, and she has to finish that expedited transcript, so we're an hour late already.

I suppose if -- am I hearing that there is not an agreement to split Kerr's testimony?

MR. GIDLEY: There is not, Your Honor. We would prefer to get Kerr on and off, and we, of course, are happy for Banakar to start now, but apparently he is not for some reason.

JUDGE CHAPPELL: Okay, let's see if this is

acceptable. We have the direct of Kerr, then we hear Banakar, and then we have the cross of Kerr. Is that acceptable?

MR. GIDLEY: Yes, Your Honor, we will make that work.

MS. BOKAT: Yes, Your Honor.

JUDGE CHAPPELL: Then let's proceed. Thank you, all.

(Discussion off the record.)

JUDGE CHAPPELL: You need you to stand up and raise your right hand, sir.

Whereupon--

WILLIAM O. KERR

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Thank you, have a seat.

State your full name for the record, please.

THE WITNESS: My name is William Owen Kerr.

DIRECT EXAMINATION

BY MR. GIDLEY:

Q. Good morning, Dr. Kerr.

Dr. Kerr, would you state your current position and title and your current employer?

A. Yes, I'm a director, PENTA Advisory Services.

Q. And sir, do you hold any postgraduate degrees?

A. Yes, I do.

Q. And what are those?

A. I have a Ph.D. in economics and also a Master's Degree in economics from the graduate faculty of the New School.

Q. And sir, just to expedite the examination this morning, we have handed you a binder of exhibits. Do you see that binder?

A. Yes, I do.

Q. Directing your attention to tab 43, could you identify for the record what tab 43 is, sir, which has been designated USX 1619?

A. That's a copy of my resume as of September of 2001.

Q. And it was submitted with your expert report in this case?

A. Yes, it would have been, yes.

Q. I just want to cover briefly then your background and leave the rest to the resume.

First, sir, do you have a background in industrial organization?

A. Yes, I do.

Q. What is that background?

A. My dissertation was on an industrial organization subject, a combination of industrial

organization and labor economics, and subsequent to my completing my graduate education, I have been an economic consultant and a teacher and quite regularly dealt with industrial organization subjects, antitrust issues and other public policy issues that require an industrial organization analysis.

Q. And where did you teach, sir?

A. I taught at C.W. Post College, part of Long Island University.

Q. And sir, do you have a background in economics in intellectual property?

A. Yes, I do.

Q. And what is that background briefly?

A. I have consulted with clients and regularly do so on the valuation of intellectual property. I've also worked for counsel in a number of intellectual property cases, patent, trademark and copyright litigation cases.

In addition, I've done research and written articles and given publication -- given seminars and presentations to economic and other professional groups.

Q. Could you give us an example of one or two of the assignments you've handled in the area of intellectual property?

A. Yes, I have -- in the nonlitigation area, I have consulted with clients who were in the process of trying to assemble transactions of -- related to intellectual property, either acquiring intellectual property or companies which possessed intellectual property or, on the other hand, companies who had intellectual property and were seeking to sell or license that intellectual property.

In those instances, I helped the client to value the intellectual property, to establish the parameters that they would use, the economic parameters and financial parameters that they would employ in either buying or selling the intellectual property.

Q. Generally, sir, how would you approach the valuation of intellectual property in connection with your work?

A. The most frequent way to do it is to use what's known as a discounted cash flow analysis to provide -- to evaluate the net present value of the intellectual property.

In addition, you would look to market factors having to do with transactions that were similar to the transaction that you were evaluating. And you may also look to factors such as the market factors and production factors having to do with the cost of the

intellectual property.

Q. Now, sir, directing your attention to your industrial organization background, have you analyzed the competitive effects of mergers?

A. Yes, I have.

Q. Joint ventures?

A. Yes.

Q. And have you done this on behalf of parties opposing and supporting mergers?

A. Yes, both.

Q. And sir, at PENTA, have you represented both plaintiffs and defendants?

A. Yes.

Q. I want to direct your attention back to some of your work in the intellectual property area.

Sir, do you have occasion to teach lawyers or members of the Bar on intellectual property economics issues?

A. Yes.

Q. Could you tell us just a little bit about that briefly?

A. Most recently, in December, I gave a -- I taught a seminar for continuing legal education, known as CLE, for lawyers in the industrial -- in the intellectual property section of the Delaware Bar

Association. I've taught similar courses in Texas, Ohio, Washington, D.C. and Virginia.

I've also taught seminars on the valuation of intellectual property and patent law, patent damages, the economics of patent law, with the Licensing Executives Society, which is a group composed of lawyers as well as other business executives whose responsibility is managing intellectual property and engaging in transactions related to intellectual property, in short, the licensing agreements and licensing executives.

Q. As an economist, have you had occasion to serve as an expert in connection with patent infringement litigation?

A. Yes, I have.

Q. Generally, what kinds of assignments have you taken on?

A. The most frequent economic and financial analysis that's required in patent litigation relates to damages, evaluating either the patent owner's lost profits or a -- or determining what would have been due under a reasonable royalty to the patent owner had the infringement not occurred.

In addition, there are other issues that crop up in different types of patent litigation having to do

with whether and to what extent the technology covered by the patent is commercially viable and has been commercialized by the patent owner.

Q. Approximately how many patent infringement cases have you had occasion to consult on?

A. Fifty, give or take a few.

Q. I'm sorry?

A. Fifty, give or take a few.

Q. Okay. And sir, were those cases in Federal Court or arbitration or both?

A. In both. Most of the -- the majority are in Federal Court, and even those that end up in arbitration often are also in Federal Court, although they're -- they -- the arbitration is an attempt to resolve the matter that was otherwise in Federal Court.

Q. In your past background with patent infringement suits, have you had occasion to review patent infringement settlement agreements?

A. Yes, I have.

Q. On several occasions?

A. Yes.

Q. And sir, do you have familiarity with the court system with respect to the handling and processing of patent infringement claims in the United States?

A. Yes, I do.

Q. What is basically the district and appellate structure for patent disputes in this country?

A. The patent infringement actions are generally brought at the or are always brought at the District Court level. The appeal then goes up to an appeals court, a single appeals court, called the Court of Appeals for the Federal Circuit that was established in the early 1980s to deal, among other things, with questions of patent law.

Q. How did the creation of the Court of Appeals for the Federal Circuit affect your economic practice, your consulting practice?

A. The Federal Circuit and other things that were happening at the time in patent law changed my consulting practice greatly, because as part of the change in the law that the Federal Circuit imposed on the patent law, the importance of economic and financial analysis in patent law became quite significant, and these days, much of my litigation practice, certainly the majority of my litigation practice, is in the intellectual property area for that reason.

Virtually every patent case now requires economic analysis of the things that I mentioned earlier. Prior to that, antitrust law was -- was --

made up almost my entire litigation practice, because that was the -- economics -- the crucial nature of economics in antitrust law. Somewhere along the eighties, the Federal Circuit, decisions made by the Federal Circuit, brought economics in a very big way into the application of patent law.

Q. Prior to your engagement in this matter, did your consulting group maintain a database on patent infringement suits?

A. Yes, we did.

Q. Can you tell us a little bit about that database?

A. I started the patent database when I helped start the firm that I'm now associated with in 1997. What we did was we sought to describe what the relationship was between patent decisions at the District Court level and at the Federal Circuit and how they've incorporated economic analysis in their decisions.

We started assembling written decisions at the District Court level that dealt with economic issues and taking information from them as to how the Court -- as to how the Court applied the economic principles in terms of damages and product definitions, reasonable royalties, as I mentioned before.

We also did that to the Federal Circuit and looked at Federal Circuit decisions in which economic analysis was prominent. We put the information that we got from that analysis into a database, and now the database contains that kind of information on every case that was decided either at the District Court level or at the Federal Circuit since 1990 through the end of -- I think we're now updated through the end of 2001, and we may not be quite there yet.

In addition, we went to a database that's maintained for the Administrative Office of the U.S. Courts by the University of Michigan, by the Research Institute of the University of Michigan. That database deals with all cases that are filed in any District Court, and the piece that we look at is all civil cases. We don't look at criminal cases.

We took that information and added that to our database. So, now we have a database that includes all -- from that all patent cases that were filed in any Federal Court, regardless of the outcome, and we're able to look at how those outcomes have affected the economic issues.

Q. You mentioned earlier that you were involved in approximately 50 patent infringement cases. How many of those have gone to trial and how many have settled,

approximately?

A. Of the 50, I would say no more than five have gone to trial.

Q. So, 45 or so have settled?

A. Yes.

Q. All right, sir. And you mentioned earlier that you've seen settlement agreements. Have you consulted parties who are about to enter into a settlement agreement in a patent infringement case?

A. Yes, yes, quite often.

Q. And what sort of engagements or what sort of work have you done in that connection?

A. As I mentioned, only about five of the cases that I've been associated with, you know, certainly one in ten, maybe even less than one in ten of the cases that I've been associated with went to trial. The others have settled, and quite often, being the economist and having done the kind of analysis that I've done for them in the case, both the client and lawyers will turn to me to help them to figure out how the settlement should be structured, what kinds of -- how big the settlement should be and that sort of thing.

And so I consult with them to try to value the settlement and the -- and in order to do that, it

requires doing what I was doing anyway on the case, which is valuing the underlying intellectual property.

MR. GIDLEY: Your Honor, at this time we would tender Dr. Kerr as an expert witness in the areas of industrial organization and the economics of patents, patent litigation.

MR. EISENSTAT: Could I have a voir dire with the witness, Your Honor?

JUDGE CHAPPELL: Yes, you may.

VOIR DIRE EXAMINATION

BY MR. EISENSTAT:

Q. Good morning, Dr. Kerr.

Dr. Kerr, do you have a medical degree?

A. No, I don't.

Q. Are you licensed as a professional in any medical field?

A. No, I'm not.

Q. Do you have any formal training in evaluating the safety and efficacy of pharmaceutical products?

A. No, I do not.

Q. Do you have any formal training in pharmacology?

A. No.

Q. Have you ever gone to law school?

A. No.

Q. Do you have a law degree?
A. No.
Q. Do you have any formal training in the interpretation of laws that regulate the marketing of pharmaceutical products in the United States?
A. No, I don't.
Q. Have you done any studies of the laws that regulate the marketing of pharmaceutical products in the United States?
A. Yes, I have.
Q. And tell me about those studies.
A. Well, in a number of the patent infringement actions that I mentioned a few minutes ago, the -- what was involved were pharmaceuticals, and as part of my work to value the intellectual property that was involved in those cases, I needed to examine how the regulatory framework, including the laws, influenced the marketing of various kinds of pharmaceuticals.
Q. Okay. Do you have any formal training in chemistry?
A. Other than high school chemistry, no.
Q. You have no degrees in chemistry?
A. No.
Q. Do you have any formal training that relates to the development of coatings for sustained release

pharmaceutical products?

A. No.

Q. Do you have any formal training that relates to the evaluation of coatings, period, for sustained release pharmaceutical products?

A. No, I don't.

Q. When you gave opinions in the past in court on patent matters, did you give any opinions that related to chemistry?

A. No.

Q. Did you give any opinions that related to coatings for sustained release pharmaceutical products?

A. No, nothing specific on the technology of coatings.

Q. Dr. Kerr, do you consider yourself in the mainstream of economic thought on industrial organization?

A. I haven't given it much thought, but certainly if there is a mainstream, I'm probably right in the middle of it.

Q. You use the same tools and methods of analysis as other economists in industrial organization?

A. Yes, I do.

Q. In one of the draft demonstratives that we were sent in preparation for your testimony, a textbook by

Gordon V. Smith and Russell L. Parr, Valuation of Intellectual Property and Intangible Assets, was cited. Do you rely on Drs. Smith and Parr text in your work?

A. I use it for the valuation of intellectual property. I use the methods in it. I don't rely on the text, per se, but I certainly use the same methods that Dr. -- that Mr. Smith and Mr. Parr use.

Q. You would rely on the methods in that book?

A. Yes, the methods in that book are the same methods that I would use to do my valuations.

Q. Do you consider that to be a reliable text?

A. In general, yes.

Q. In another of the draft demonstratives that complaint counsel was sent in preparation for your testimony, a textbook by Robert Pindyk and Daniel Rubenfeld entitled Microeconomics was cited. Do you rely on the text by Drs. Pindyk and Rubenfeld in your work?

A. I haven't, no, but I know of the book.

Q. Do you consider it a reliable text?

A. I haven't read it, so I'm not sure.

Q. Do you know why it was cited in one of your prepared demonstratives?

A. No, I don't.

Q. Are there other microeconomic texts that you do

use in your economics work?

A. It's been years since I've looked at a microeconomics textbook, not in -- because I practice microeconomics, and I don't necessarily have to go back to textbooks to figure them out, figure out the issues that are involved. I have several microeconomics textbooks in my office, and if I need a refresher and use one as a reference, I will pull it out, but I have the Pindyk text.

Q. Are there -- of these microeconomics textbooks you have in your office, are there microeconomics textbooks there that you consider reliable?

A. Yes.

Q. And what would those be?

A. The one that I refer to most often is one that I used in graduate school, which is probably now somewhat out of date, but it's by Charles Ferguson.

Q. Charles Ferguson?

A. Yes.

Q. And do you know what the title is?

A. Microeconomics.

Q. Are there any others?

A. I have one that I used when I was a graduate teaching assistant by George Stigler.

Q. Is that also entitled Microeconomics?

A. I believe so. I can't remember the exact title.

MR. EISENSTAT: At this time, Your Honor, we have no objection to Dr. Kerr being recognized as an expert in the areas that were specified by respondent's counsel.

MR. NIELDS: We have no objection either, Your Honor.

JUDGE CHAPPELL: Thank you, Mr. Eisenstat and Mr. Nields. The motion is granted.

MR. GIDLEY: Thank you, Your Honor.

DIRECT EXAMINATION (cont)

BY MR. GIDLEY:

Q. Dr. Kerr, are you familiar with the June 17th, 1997 agreement between Upsher-Smith and Schering-Plough?

A. Yes, I am.

Q. Sir, have you reviewed it in connection with your work in this case?

A. Yes, I have.

Q. Now, is that agreement facially anti-competitive in your view?

A. No.

Q. Why not, sir?

A. There's no way to read that agreement and reach

a conclusion about the pro or anti-competitiveness of the agreement without doing a significant amount of other analysis.

Q. And sir, can you give us a general introduction to the issues that you think are relevant to evaluating whether or not that agreement is anti-competitive?

A. Well, that agreement, as I'm sure is clear from the prior testimony, includes a series of subagreements, if you will. One of them, one group of agreements, has to do with licenses that were provided for intellectual property, products owned by Upsher-Smith, in exchange for a royalty to Schering-Plough.

In addition, the broad agreement covered a settlement agreement that resolved patent litigation between the two parties. Each of those agreements and subagreements -- each of the subagreements in the larger agreement have anti and -- potentially anti and potentially pro-competitive effects. Without analyzing the anti and pro-competitive effects of the subgroups, you're not going to be able to determine whether the overall agreement is anti or pro-competitive on net and whether the effect of that agreement is going to be pro-competitive or not.

Q. Are you familiar generally with the '743 patent

that Schering-Plough holds?

A. I've read it. I know what it is.

Q. And sir, considering that patent in connection with the agreement, what are some of the issues that you have reviewed in this case?

A. Well, the '743 patent is the patent under which Upsher and Schering were engaged in litigation back in the period prior to the settlement in June of 1997. The settlement relates to ending that agreement -- ending that litigation. It describes the litigation, and under the terms of that settlement, the '743 -- the litigation covered the '743 patent and prescribed -- or the issue that was being fought was whether Klor Con M20, the first of Upsher-Smith's Klor Con M products, infringed or did not infringe the '743 patent.

One thing I noticed in the settlement agreement is that the settlement agreement covered both Klor Con M20 and Klor Con M10, which is not a product that was included in the underlying litigation. So, the settlement agreement allows Upsher-Smith to start selling a product called Klor Con M10 in September 2001, even though it was not subject to the underlying litigation. The settlement, in fact, allowed Upsher-Smith to bring both products onto the market earlier than it would otherwise have been able to do.

Q. Is that feature pro-competitive, the M10 element of the agreement?

A. Yes, certainly bringing the M10 into it and allowing that entry to occur in September 2001 is likely to be pro-competitive, as is the agreement to allow Klor Con M20 to enter the market in September 2001.

Q. Sir, let me direct your attention to the exhibit binder and direct your attention specifically to tab 1. That's an exhibit that has the designation USX 1011, 1-0-1-1. Do you see that?

A. Yes, I do.

Q. Sir, can you tell us a little bit about the basic chronological facts that relate to the '743 patent and the settlement at issue in this case, the June 1997 settlement?

A. Well, the '743 patent expires on September 1st, 2006. That's what's illustrated on this time line. The settlement agreement was entered into in mid-June of 1997. That's when the litigation was set to go forward, the trial was set to go forward. The litigation had been going on for some time.

The settlement agreement allows the entry of both Upsher-Smith Klor Con M products, the 10 and the 20, to begin -- to be free of the patent restriction

and to begin selling as of September 1st, 2001.

Q. And sir, you said September 1. This slide, 1011, is rounded, is it not, in terms of the dates?

A. Yes. Yes, it is -- it appears to be. It's done in terms of months. It looks to be as of July 1st beginning -- July 1st of 1997 being the zero point rather than June 17th or June 18th, which is when the trial would have begun, and so it is rounded to the beginning of a month, and in that sense, it -- if we do round the beginning of the month, the amount of time that was left on the patent as of July 1st, '97 is 110 months.

Q. And directing your attention to note 3, when did the patent expire, the '743 patent?

A. I'm sorry. The patent actually expired September 5th or will expire September 5th, 2006.

Q. Directing your attention to tab 2, USX 1590, sir, could you describe what's going on in this exhibit?

A. This exhibit simply illustrates the amount of -- the proportion of time that remained on Schering-Plough's patent -- and, in fact, still remains, the patent's still in effect -- that remained on Schering-Plough's patent as of the proposed start of trial, which was June 18th, 1997, and it illustrates

that the amount of time taken off the patent by the settlement was 55 percent of the remaining life, roughly.

Q. Let me turn your attention to tab 3, USX 1591, a slide entitled Competitive Analysis of a Hypothetical Patent Settlement. Dr. Kerr, how did you use this slide in your analysis?

A. This is an attempt to illustrate the kind of competitive analysis that I engaged in as part of this case. I was asked to analyze the competitive effects of the settlement portion of the agreement, the agreement between the two parties to allow Upsher to be free of patent restriction as of a certain date, and it is -- I did that in terms of this time line chart, which is presented in tab 3.

Q. And USX 1591, is that sort of a stylized or hypothetical slide?

A. Yes, it's a -- it represents a time line. It's a single axis graph with the axis being time from zero to ten years.

Q. In your view, is the time element an important element in evaluating the June 17, 1997 agreement?

A. Yes, it's very important.

Q. May I direct your attention to USX 1592 found at tab 4, sir?

A. Yes.

Q. And can you describe for us what's going on in this exhibit?

A. Yes, 1592 starts to get to the analysis. The original time line illustrates the situation that was in place with a hypothetical patent owner. The patent owner was -- had ten years left on their patent. They -- the patent gives them the right to be the sole practitioner of the technology or the sole producer of the product that's covered by the patent, and from a public perspective, we do -- we are at least in part in an antitrust analysis obligated to look at the public's perspective. The public's perspective at that point was that the only way they could get the patented technology was to go to the -- to go to the patent owner. It was under their control.

The second slide, though, puts us into the situation that we're trying to analyze here, and that is instead of the patent owner being alone, we now have a prospective entrant who is attempting to enter, and we now have to bring in some facts from this case, and we are therefore talking about an entrant who is a pharmaceutical producer trying to bring in a generic product, and the patent owner is an owner of a pioneer drug.

What we're representing here is the fact -- in a stylized way the facts of this case. Settlement is entered into between the two parties to resolve the patent litigation, and that's illustrated here by splitting the time on the patent, allowing the entry to be free of patent restriction after five years.

Q. And in this stylized exhibit, what are you comparing the settlement to?

A. We need here to compare it -- that's the -- the competitive analysis that we're doing in this case is comparing the settlement, the ability of the entrant to come in, with the outcome of the litigation, because if the settlement is prohibited, what we end up with is the litigation, and determining whether the settlement is pro-competitive or anti-competitive requires determining -- comparing it with something else, and it requires determining whether the settlement is better or worse for competition than continuing the litigation would be.

Q. What does the phrase "End of Patent Restriction" mean in this slide?

A. It means that as a result of either the litigation or the expiration of the patent or as a result of the settlement agreement, the entrant can be free of the patent restriction and therefore be able to

come into the market if they're able to do all the other things that they need to do to get into the market. This is designed only to look at the patent restriction.

So, for example, we're in the -- this is a pharmaceuticals industry example. Freedom from patent restriction doesn't necessarily mean what we would otherwise call entry. In order to enter, the generic manufacturer also has to deal with FDA regulations. They have to have a distribution network capable of selling the product. They have to manufacture the product. They have to establish a manufacturing operation capable of producing sufficient quantities and getting it distributed.

So, this whole analysis just deals with the settlement agreement, and the settlement agreement deals with the -- with the rights of the generic and the patent owner under the patent. It's limited to that.

Q. In your experience, sir, do generic firms in the pharmaceutical industry, do they enter the market when patent infringement litigation is pending typically?

A. No.

Q. Why not?

A. Well, there are a number of reasons, and one of the reasons -- one of the important reasons is this interplay between the patent law and the regulatory system that affects pharmaceuticals. If patent infringement is alleged by a -- by the owner of a patent for a pharmaceutical, the FDA under the Hatch-Waxman Act is not able to grant approval, and therefore, if they can't grant approval, they can't -- the generic is not able to come into the market.

Even if that's not the case and we -- and there can be situations where a generic is free and able to come into the market under the FDA, for example, during an appeal process of a patent, a pending patent litigation, it would be very difficult, I mean very unlikely, that a generic would come into the market if they perceived that they had a risk of losing the patent litigation.

Q. Given your work in damages, what kind of economic incentive or exposure would the generic firm face if the patent infringement litigation is not resolved?

A. They would -- they would face the kind of risk that would be intolerable in most instances, and that's because a patent -- a generic producer coming into the market, finding themselves later to have infringed the

patentee's patent, would face damages that are likely to be far in excess of what they would stand to earn coming into the market.

Q. Why is that? What's the measure of damages in an infringement action?

A. Well, that's because the primary measure of damages in a patent infringement action is the losses experienced by the patent owner, and therefore, if a -- if a generic comes in, they will likely end up, if they're convicted of patent infringement and they use the damage analysis, they will end up having to compensate the patent owner for the substantial losses that they would face.

And what happens -- I guess let me explain this a little better -- a branded manufacturer generally loses two things when a generic comes in. Prices tend to fall and/or market share falls. Either way, there are substantial losses from the branded manufacturer, much more than the generic stands to gain coming into the market.

Q. So, it's a lost sales measure to the patent holder. Is that the measure?

A. Yes, the way the damages are generally estimated is the lost profits of the patent holder, and they generally tend to be much more substantial than

the gains of the generic entrant.

Q. Turning your attention to the next tab, slide USX 1593, what do the words "Average Litigation Result" mean and what is this slide describing, sir?

A. This illustrates the nature of the analysis and a little bit of the difficulty of the analysis. On the last slide, remember, we had to compare the outcome of the settlement with respect to the entry of the generic with the outcome of the litigation. Well, the outcome of the litigation -- there is no "outcome of the litigation." There are at least two outcomes of litigation. The generic manufacturer could win or the pioneer could win. Those are represented by the dotted lines illustrated on that -- on the chart.

So, it's hard to evaluate the competitive effects of a settlement compared to the litigation, because if you're -- if the settlement is compared with those outcomes that favor the pioneer, clearly the settlement is pro-competitive, because you end up with entry prior to when the expiration of the patent would be. If you compare it to those outcomes that favor the generic, well, then it appears that the settlement delays entry.

This slide illustrates a method of analysis which I did use in this case, and that is to find a

single point that represents the outcome of the litigation. If we have a single point that represents the outcome of the litigation, we're able to compare that to the settlement and determine whether relative to the litigation the settlement is pro or anti-competitive, delays or accelerates the entry of the generic.

Q. In this case, what kind of analysis did you employ? And I direct your attention to USX 1594, the next tab.

A. What I did was attempted to find the average outcome of the litigation, if you will, that was illustrated on the prior slide, and I did that by employing an analysis that's variously known as a decision tree analysis, a fault tree analysis. It's a statistical procedure that allows one to look at a significant number of variables, different kinds of outcomes, and bring them down using a probability analysis to a single average outcome.

What I did was I identified what would have to have happened in order to resolve the litigation and how many different ways can the litigation be resolved -- could the litigation have been resolved, and if the litigation was to be resolved in each of those cases, when would the patent restriction on the

generic in this case have been lifted as a result of the outcome of the litigation?

Now, there are a myriad -- you know, an infinite number of possible outcomes of the litigation. Sitting there in June of 1997, looking forward -- infinite probably is too big a number, but there are a large number of options that could have happened, and we have to have some way of evaluating all of the significant paths into the future and bringing them all down to a single number, an average outcome.

Q. Let's go through the factors and assumptions you employed. On 1594, the first line reads, "Each party's chance of success, 50%."

What assumption or factor did you apply there?

A. It is -- it is -- 50 percent is the factor that I chose. There are two basic questions you have to answer to deal with this kind of an analysis, and that -- the first question is, how likely is it that either of the parties would succeed? The second question is, if the generic succeeded, when would the litigation be resolved so that the generic would be free of the patent restriction?

The first factor on that list deals with the first question. We have to come up with a number that says how likely it is that either party would succeed.

In this case, I've looked at the record, I've looked at the testimony, I've looked at Dr. Bresnahan's report, and it seems pretty clear that there is no evidence -- it's very clear to me that there's no evidence here that either party had a -- had what would be considered to be a slam-dunk in the litigation. Neither party was going to walk in with a great deal of certainty and walk out. So, to represent the -- to represent that, we chose 50 percent as each party's chance of success.

Q. But is it ultimately an assumption or have you tried to objectively figure out who would win the underlying patent infringement case?

A. No, it's ultimately assumption. I've read the record to see whether there was anything in the record that tells me one way or the other, but I've -- I would pass on to the patent lawyers among you all to figure out what -- what the underlying merits of the patent case were in 1997.

Q. The next line, "Summary judgment decision, 10%," what assumption is there?

A. Well, this is the first one of the next set of inputs to the probability model, and it deals with the timing of the litigation. As opposed to who's going to win or lose, it goes to the timing. The first step in that analysis is to identify all of the hurdles that

have to be crossed in order to get from June 1997, prior to trial, to the end of the litigation, and for our purposes, we're using the end of the litigation as a final ruling by the Federal Circuit.

Summary judgment has to be -- decisions have to be considered. The trial has to be considered. Post-trial motions have to be considered. Once the post-trial motions are done, the Court has to issue a ruling. That ruling then has to be carried on to appeal and so forth. So, I need an input that will allow me to set a time and a probability for each one of those events.

Q. The next --

A. And the first one is the summary judgment decision.

Q. Excuse me.

A. And which I -- which I have taken to be a 10 percent probability that the court would have ruled and disposed of the case on summary judgment.

Q. "Length of trial or retrial, 1 month." Why did you choose one month?

A. That, by the way, is a calendar month, doesn't mean court days. My experience has been that that's a reasonable amount of time to estimate for a patent trial. I also spoke with many of my clients who are

patent lawyers, and one month seemed to be a reasonable number.

Q. The next factor applied, "Probability of losing party appealing, 100%."

A. That deals, as it says, with the probability of the losing party appealing. Whoever loses would appeal is 100 percent. I've assumed that, again, but it's based on experience and, again, discussion with my clients, who are litigation counsel, that it's very likely that whoever loses, if in this case it was Schering-Plough losing, that they would appeal, and in Upsher-Smith's case, I've assumed that there's 100 percent chance that they would appeal, and I think that's a very conservative assumption, particularly with regard to Upsher-Smith.

Q. Why is that?

A. If Upsher-Smith were to lose at trial, they would be faced with a decision to appeal knowing that it was going to cost them a great deal more money to go forward with the appeal, and if the appeal drags on, what they're going to be faced with is eventually getting to the Federal Circuit, maybe getting a decision in their favor, and I guess it's conceivable that a Federal Circuit decision could allow -- could -- in their favor might let them into the market, but at

least as likely as a Federal Circuit decision in their favor would do nothing more than get them back to the District Court level for a new trial.

And the implication of that is that by the time the ultimate resolution of the litigation occurs, it may not be worthwhile for Upsher to go forward. So, it would be clearly a business decision on the part of Mr. Troup and the management of Upsher-Smith whether it would -- if they lost the trial in June of 1997, would they have gone forward? And it's -- although I -- I think that they would have wanted to, I'm not sure that as a business matter it would have made sense for them to do so, but in any case, I've assumed that there is 100 percent chance that they would go forward.

Q. The next factor, "End of trial to appealable ruling, 90 days," what is that based on?

A. Again, that's based on my experience and discussions with counsel. I've looked at -- I've been involved in a great number of cases, a significant number, and have knowledge of a significant number of cases that have been decided, and 90 days is I think a reasonable estimate of how long it would take a -- the average district court judge to finish an appealable ruling after the trial.

Q. The next line, "Appealable ruling to CAFC

ruling, 1 year, 7 months," what is that based on?

A. That is, again, based on my experience and discussions, but in addition, I have the advantage here of being able to study a large number of patent cases that were both decided by a District Court and then -- and decided subsequently on appeal by the Federal Circuit. They are cases that are in my database and in the database that we used from the Administrative Office of the Courts, and the 19 months or the one year, seven months is the average time that the cases in our database took to get from the date of an appealable ruling by a District Court to a final ruling by the Court of Appeals.

Q. Approximately how many cases are in your database, patent cases?

A. 250-260.

Q. The next line, "Probability of remand by CAFC, 36%," where does that come from, sir?

A. That also comes from the database. As I mentioned, we have -- a part of our database traces the decisions that are -- that the Federal Circuit issues on patent appeals, and it works out that roughly 36 percent of the cases in the period that we were -- that we had data for at the time were remanded by the Federal Circuit for further action at the District

Court level.

Q. And the final line, "CAFC remand to trial, 6 months," where does that come from?

A. That's an assumption based on my experience and, again, based on talking with patent litigators about the amount of time that it takes to get back on the District Court docket once a Federal Circuit decision orders it back.

Q. And I direct your attention to the next slide. How does the concept of sunk costs relate to your work in evaluating this litigation scenario?

A. Well, it has a number of implications for the case. The most recent one that I spoke about, though, is the business decision I mentioned that Upsher-Smith would face -- would have faced had they gone through with the litigation and lost at trial and decided whether to appeal the case or not. It's a good illustration of sunk cost as a -- from an economic perspective.

The concept of sunk cost explains why what otherwise might be seem to be a -- an incentive to go forward after you have made great investments in a particular area is not quite that incentive, because the money's already spent. So, for example, the fact that Upsher-Smith had already by this time sunk a

substantial amount of money into developing the Klor Con M products and had spent $2-plus million to get to the point of trial, if they had gone through the trial, there probably would have been close to $3 million worth of costs on top of the development costs of Klor Con.

There's a tendency to think that once you get that kind of investment momentum going, you will go forward all the time to an appeal, but if you're -- but from a business perspective and from an economic perspective, that's not the kind of incentive that works, because those costs are sunk. You're always looking forward. You're always looking to say, if I go forward, what do I have to do? Do I throw good money after bad? Do I, as the slide says, let bygones be bygones and ignore the sunk cost, always look forward?

So, as a practical matter, that business decision could presumably not be influenced by the fact that you've sunk all these costs.

Q. Let me direct your attention now to tab 8, and I show you USX 1595. Is that your decision tree?

A. Yes, that's the path analysis. That's the results of the work that I did, taking those inputs that we've just reviewed, incorporating them into the path analysis, and this is an illustration of the path

analysis.

Frankly, the calculations aren't done in this. This is just a manifestation of it, but there's an underlying model that does the calculations. As an illustration, though, it's useful, because it lays out graphically how the analysis works.

Up at the top, we start with the District Court decision. The District Court decision could be, going to the left there -- and it's very difficult to read, I apologize for that -- but going to the left, you go to the summary judgment. Would the District Court decide on summary judgment to dispose of the case? There's a probability for that.

If they did -- if the court did decide to dispose of the case on summary judgment, there's a 50 percent chance that they would -- that the decision would be for Upsher and a 50 percent that the decision would be for Schering.

If the decision goes to Schering, that means -- it doesn't end the trial, it means you'd go to trial, because the motion that was pending was an Upsher motion, and so forth. As you go step by step through that -- through that path analysis, you ultimately get to the end of the litigation. The ends that are illustrated in this diagram are the ones that are

colored in yellow.

Q. I see.

A. They get you to a final date of resolution of the litigation.

Q. Let me show you, sir, USX 1596, which is the next slide in your book, Results of Competitive Analysis. What results did you reach with your decision tree analysis of the litigation?

A. I computed the single average date of resolution of the litigation to be February 2003. That accounts for all of the outcomes that would have favored Schering, all of the outcomes that would have favored Upsher-Smith, and establishes a time for each one of those potential outcomes, averages the time together and ends up coming up with an average date, and the average date of the litigation resolution options is February 2003.

Q. And if Schering-Plough won the patent infringement litigation, what's the outcome in your model and your decision tree analysis?

A. For any final resolution that favored Schering-Plough, of course, the end date, the date at which -- at which Upsher-Smith would have been free of patent restriction, would have been the final expiration of the patent, which is September 5th, 2006.

Q. And is that taken into account in the February 2003 number, sir?

A. Yes. In fact, in the model that we used, there were eight outcomes that favored Upsher-Smith and seven that favored Schering-Plough. All of the seven outcomes that favor Schering-Plough get you to the September 2006 date. The eight -- of the eight outcomes that favor Upsher-Smith, two of them happen between September 2001 and February 2003, and the other six occur sometime between the date of the trial, which was June 18th, 1997, and September 2001, the settlement date.

Q. So, how does that compare -- what's the conclusion here?

A. Well, the conclusion is that the settlement date, which was September 2001, allowed Upsher-Smith to be free of the restriction of the '743 patent prior to the time that such restriction would happen -- would occur on average had the litigation gone forward, and in short, the settlement accelerated the potential entry date by 17 months.

Q. And again, all of this is premised on a 50/50 assumption on the objective merits of the suit?

A. That's right.

Q. And directing your attention to the bottom of

the page, this analysis does not take into account regulatory approval or manufacturing ramp-up. Is that correct?

A. Yes, that's right.

Q. Directing your attention to the next page, which is slide USX 1597, sir.

A. This is an illustration -- I'm sorry.

Q. And what -- I'm sorry, what does it illustrate?

A. It's an illustration of the original time line that we went through with the dates that we have estimated based on the probability analysis, and it shows that there's a significant acceleration. The settlement involves Upsher-Smith being free of the patent restriction better than halfway through the life of the patent and significantly earlier than the average outcome of the litigation would have been, and therefore, a consumer looking at this, the public interest in this litigation would certainly be to select the settlement over the average litigation result.

Q. Sir, is your analysis conservative of this litigation outcome?

A. Yes.

Q. In what sense? What factors make it conservative in your view?

A. Well, I mentioned -- I've already mentioned one way, and that is that by assuming that both parties had 100 percent chance of appealing, I have stacked the deck in favor of Schering, because, in fact, I believe there's less than 100 percent chance of Upsher-Smith appealing, and therefore there's -- there is a good chance or there's a -- there's not as good a chance as I'm allowing for that Upsher-Smith would have appealed and could have won on appeal, and that removes -- that puts in too many possible outcomes for Upsher-Smith.

If we go through the assumptions, there are a number of other assumptions that are -- that are conservative. In fact, the overall analysis that I did, as I mentioned, in the analysis that I finally did, we simplified the analysis considerably by limiting it only to 17 possible outcomes. There are a great many more possible outcomes to the litigation. The ones that I've excluded are all outcomes that would have pushed the date out.

For example, I did not allow for two appeals to the Federal Circuit, and it's quite common in patent cases that a case is decided by the District Court, goes to the Federal Circuit, is remanded to the District Court, and following the second District Court trial, there's another appeal. I didn't allow for

that, because that would have just built a loop into my calculations that would have pushed the time out.

Another --

Q. What about other litigation tactics, like moving for certiorari with the Supreme Court or seeking a rehearing with the circuit court, were either of those considered?

A. Neither of those are included. Again, they would have pushed the time out. I didn't allow for the prospect of an en banc hearing at the Federal Circuit, which would have pushed the time out. So, in -- for all those reasons, the -- and for ease of presentation and simplification in calculation, I made those assumptions to move it in, but they are all -- they all end up being conservative with respect to the outcome.

Q. Let me direct your attention now to the second part of your analysis, the valuation, if you would turn to tab 11 or watch it on the screen, sir, and I show you USX 1598, and it's a slide from Smith and Parr.

Why did you select this quote from Smith and Parr? How is this relevant to this case?

A. It's a description of what I consider to be the most common and in my experience is the most common method of valuing intellectual property, and as the underlying sections tell you from this quote, the most

important thing to do is look to the future benefits that the owner of the intellectual property is likely to get. That's how you start your valuation.

But secondly, it's necessary, because this is -- this inevitably involves a stream of income over time, that stream of income needs to be compressed into a single number, and it has to be done, therefore, at a single date in time.

The second point is that it has to be -- the value can only be expressed relative to a given moment. So, in order to do this valuation, you have to look into the future to determine what the cash flow streams are going to be, and then you have to bring those streams back to the future in some way so that you can express it as a single number at a single point in time.

Q. And the quote concludes, "'as of' a specific date."

Is there a specific date that you've done valuation work in this case?

A. Yes.

Q. What is that date?

A. It's June 17th, 1997.

Q. And why did you choose that date?

A. Because that's the date of the settlement.

Q. And did Dr. Bresnahan also agree that that was the right date to look at?

A. Yes, I believe he did.

Q. Let me direct your attention to the next slide, which is a demonstrative you prepared on net present value. Briefly, what is the concept of net present value, sir?

A. The net present value is the method that one uses to do the kind of valuation that I've just described. It involves looking at the cash flow into the future, discounting that cash flow. That's a financial procedure that -- sort of the reverse of an interest calculation, bringing the calculation back to present value, recognizing that cash received or paid ten years from now is worth less to the individual now than cash paid tomorrow.

So, it is the way to do what I mentioned before, which is look into the future, look for the cash flows, and bring it back to the present.

Q. By the way, is this mainstream economics or exotic, this concept of a net present value?

A. Oh, it's mainstream analysis. It's the way it's done in economics and financial analysis.

Q. Is it common in business?

A. Oh, yes. Yes, it's -- any investment is likely

to be subject to a net present value kind of analysis.

Q. Let me direct your attention to the next slide, which is a demonstrative on discount rate, and can you describe what a discount rate is in the context of your valuation work, sir?

A. Yes. Remember, I mentioned that we have to look into the future and discount that future stream back to the present. To do that, you use a discount rate, which again is analogous to an interest rate in reverse. It -- you look at the future. You see a $10,000 cash flow ten years from now. You bring it back using the discount rate.

The discount rate is composed of -- generally composed of two pieces. One piece of the discount rate is merely to reflect the time value of money, the fact that in the future, that you have to wait to have the money if you are going to get it ten years from now, and that's generally considered to be a risk-free portion of the discount rate.

In addition, a component of the discount rate that is required is to reflect the riskiness that ten years from now, whoever has promised to pay you that money, will not be around. So, there's two components of it. One is, if you could think of it this way, if there's a payment promised ten years from now and you

are absolutely certain it's going to happen, you wouldn't have to have the second component, but you still would not consider that to be dollar for dollar what the value is of a payment tomorrow.

Q. Does everyone have the same discount rate, or do different firms and entities have different and varying discount rates they apply to capital investments?

A. There are a great many discount rates that would be -- I wouldn't say everyone has different discount rates, but -- but each individual would have -- should -- each individual, each organization would have a discount rate that's appropriate to them --

Q. Let me direct --

A. -- because of the risk factor.

JUDGE CHAPPELL: Mr. Gidley, let's pause just for a second.

MR. GIDLEY: Sure.

(Pause in the proceedings.)

JUDGE CHAPPELL: Go ahead.

BY MR. GIDLEY:

Q. Let me direct your attention to slide USX 1016, and I am going to ask you a variety of questions about the June agreement.

Are you familiar with the term "reverse payment" in the context of this litigation?

A. Yes.

Q. And sir, are you familiar with the Bresnahan report? Is that correct?

A. Yes, I am.

Q. And in the June 1997 agreement, what were the bundle of rights or licenses that Schering-Plough received from Upsher-Smith?

A. They reflect licenses that were provided to Schering to sell in various areas and under various different terms a number of products that Upsher-Smith had. In short, it was Upsher-Smith's intellectual property that was being transferred from Upsher-Smith to Schering-Plough. It covered six products, and those are represented on that slide.

Q. All right, and those products are Niacor-SR, pentoxifylline, Prevalite and Klor Con 8, 10 and M20. Is that correct?

A. Yes, that's right.

Q. And were there also supply agreements that were granted to Schering-Plough?

A. Yes, in addition to the licenses, as part of the license agreement, Upsher was -- Upsher gave to Schering-Plough certain rights to supply it the product

at cost.

Q. Let me show you the next slide, USX 1601, Expected Economic Value of Niacor-SR License to Schering-Plough. Can you tell me first, what's the source of the data here in general?

A. It's analysis that I did of the record in this case that allowed me to find information on -- going back to the definition -- the future stream of revenues and costs that would be attendant with the future sale of Niacor-SR.

Q. Sir, are you familiar with three "up-front" payments, royalty payments that are included in the June 1997 agreement?

A. Yes, I am.

Q. And sir, where do those appear in your analysis? Where can we find those? I know that the numbers are a bit hard to read on the monitor.

A. About halfway down the page, if you look on the left-hand side where the titles are, you'll see, "Up-front Royalties." Those payments are reflected in the -- in that row, the first payment being included in 1997 for $28 million, the second payment in 1998 for $20 million, and the third payment in 1999 for $12 million.

Q. And the revenue and cost numbers, where do they

come from? What's the source?

A. The revenue and cost numbers come from a contemporaneous valuation of the expected benefit of Niacor done by certain Schering-Plough executives in June of 1997.

Q. Did these numbers appear in the Schering-Plough board of directors book?

A. Yes, they did.

Q. And sir, you talked about the up-front royalties. I see also milestone payments and running royalties with positive values.

A. Yes, that's right.

Q. And I see running royalties of $4.5 million, $8.0 million, et cetera.

A. Yes.

Q. And what assumption is being made there by the Schering-Plough employees?

A. Well, the Schering-Plough employees didn't do those. Those are calculations that I did. I read the settlement agreement, saw the terms of the licenses that were offered under the settlement agreement in the June 17 agreement, and applied the terms of the licenses, including the running royalty and milestone, to the figures that were put forward by Schering-Plough.

Q. What was the discount -- I'm sorry.

What is the discount rate that Schering-Plough ordinarily would use in 1997 for capital investments?

A. I understand that Schering-Plough generally used a 13 percent discount rate. Occasionally I understand that they would go as high as 15 percent.

Q. And sir, you -- what discount rate are you using here in this spreadsheet?

A. I used a 25 percent discount rate.

Q. Why did you select 25 percent?

A. My original assignment was not to value this in terms of what Schering-Plough or Upsher-Smith considered the Niacor to be. It was to determine whether the valuations that were done in 1997 were reasonable from an outside perspective. My experience is that when doing that kind of valuation, I would think that a discount rate in the 20 -- 18 to 20, maybe 22 percent range was what I would use looking at it from outside.

And the reason for that is because I don't know, being outside and having -- not having a specific buyer or seller of intellectual property in mind, I don't know what the cost of capital would be, and that's an important consideration. I don't know what the risk preference of the prospective licensor or

licensee is. Therefore, I'm doing this from a -- in an abstract way, and I chose 25 percent as being the outside range that I would expect to be used if I were doing this outside for a -- for a client undetermined.

Q. What's this number, "Economic value as of June 1997, 110.8"? What is that?

A. That's the single figure that was referred to in the definition of this kind of an analysis earlier on. It's the value of the future benefits that were laid out on the chart above discounted back to June of 1997 using a 25 percent rate. So, it's expressing that future profitability that's illustrated on that chart in nominal dollars, in the dollars of the year that the numbers appear under, bringing it back to 1997.

Another way of looking at it is it's the sum of that bottom line. If you add across that bottom line, you will get 110.8 million.

Q. And it's expressed in millions, is it, sir?

A. It's expressed in millions of dollars.

Q. So, it's $110.8 million?

A. Yes.

Q. And it's using 25 percent discounted cash flow?

A. Yes.

Q. And if you increase from 13 or 15 percent to 25 percent as the discount rate, what is the effect on the

bottom line number in this spreadsheet?

A. This spreadsheet is a much lower number than you would get if you were to use the discount rate that either Schering-Plough or Upsher would typically use. As I mentioned, Schering's typical rate would be 13 percent. The number, if you used a 13 percent discount rate, would be much higher.

Q. Do you believe that this makes your analysis conservative?

A. Yes, oh, absolutely.

Q. Directing your attention to USX 1602, have you performed a sensitivity analysis on these Schering-Plough numbers?

A. Yes, I have.

Q. All right. Could you take us through that analysis briefly?

A. Yes. The -- the top line of that chart illustrates just the point that you were making a minute ago. I used a 25 percent discount rate to do my analysis, and you'll see there in the yellow shaded box the same number that was on the prior page, the $110.8 million. That's the results of my valuation.

If I had used a different discount rate, if I had used 20 percent, which I think is a -- is probably more the middle range of what I would see as reasonable

from an outside perspective, the value would be higher. It would be $155.9 million.

If I had used 15 percent, which is a range -- a rate that both Schering and Upsher have used periodically to do valuation of internal investments, the discount rate -- the discounted cash flow would come to be $220.2 million.

And if I were to use the 13 percent that Upsher -- I'm sorry, that Schering typically used to do their evaluation, the number would be $253.4 million.

Q. Sir, what is a sensitivity analysis, just in general terms?

A. A sensitivity analysis is a way of testing I guess how sensitive a model is to changes in the relevant variables. So, the three relevant variables in the case of this analysis are the future revenue flows, future cash flows and the discount rate. So, this test, this sensitivity test that I've done that's illustrated on this page changes each of those variables in significant ways to show whether the results, the ultimate results, are changed significantly by the -- by the changes in the figures.

Q. When some of us stare at numbers like this, we wonder, where is the $60 million or the net present value of the up-front payments? Where is the so-called

$60 million in this case reflected in the sensitivity analysis?

A. Well, the $60 million isn't here anymore. It's on the prior page.

Q. Well, why don't we go there, and just show us where the $60 million is in relation to the $110 million that you calculated.

A. Yes, the $60 million is accounted for in the original cash flows. It recognizes that Schering -- again, look at that up-front royalties line, the payments that I described before are the $60 million. In 1997, the first payment would be $28 million, then 20, then 12. So, the ultimate number, the 110 million, is the value of the Niacor license after paying the $60 million up front, and, in fact, after paying the $60 million up front, which works out to be a good deal less than $60 million, because, in fact, it's three payments scattered over time rather than a single one, and after taking out the milestone payments and all the running royalties. So, those figures on the next page don't have the $60 million in it anymore. This is after paying the $60 million the value that the license has.

Q. So, in other words, these numbers are net in two ways. First, this is a net present value as of

June 1997 for Niacor-SR?

A. That's right.

Q. And second, it's net of the up-front payments, is that correct, for USX 1601?

A. Yes, one of the things that it's net of is the up-front payments. It assumes that they have been made.

Q. All right. And directing your attention to 1602, all of the numbers there in the sensitivity spreadsheet, all of those are net of the up-front payment. Is that correct?

A. Absolutely.

Q. And they're also net of other royalties, running royalties and so forth?

A. Running royalties, milestones and everything else, yes.

Q. Is this a common way for businesses to look at a future investment, to do a sensitivity analysis?

A. It's very common, yes.

Q. You've seen this before?

A. Oh, sure, sure.

Q. Now, sir, what have you done -- what other methods have you employed to determine or scrutinize the value of the Niacor-SR license as of June 1997?

A. Well, I can -- in addition to varying the

discount rate, I varied the costs and revenues that were in the original assumptions. I increased the costs by 20 percent on the first line there, and that shows the effect on the value of the license. Of course, it reduces it. If you go to the third line, it shows the effect of decreasing the revenue by 10 percent. If the revenue was overestimated by 10 percent, that would artificially increase the value. So, if you look at that line, those values are lower than the values on the top line.

And then I did both. I decreased revenue by 10 percent and I increased costs by 20 percent, and even when you do that and use the 25 percent discount rate that I used, which was, again, a very conservative one, this product or the value of this product, of this license, is $68 million over and above all of the royalty payments that we mentioned before.

Q. And again, net of the up-front payments, running royalties, et cetera?

A. Net of the $60 million paid as up-front royalties, yes.

Q. Now, USX 1601 and 1602 relate to the value of Niacor-SR. Is that correct?

A. Yes, they do.

Q. And were you able to test the value of

Niacor-SR as of June 1997 against any other objective data?

A. Yes, I did. I was.

Q. What was that data?

A. I did two things. One is I -- both of them relate to other things that were going on in the market that related to Niacor during that period. One is I looked at the history of negotiations and contacts that Upsher-Smith had been making to try to market the Niacor license in Europe during roughly this period, and the other was I looked at a product that was just entering the market that was similar to Niacor and was produced by a company called Kos, and I looked at the success and public record on the ability of this company to put out a product that was going to be successful.

Q. And the Kos Niaspan product -- and I know you're not a doctor -- is similar to the Niacor-SR product?

A. Yes, it is.

Q. All right. Let me direct your attention to tab 17, and that's USX 1606. What is USX 1606?

A. USX 1606 is a graph that illustrates one of the findings that I obtained in doing the analysis I described. What I was able to do was I was able to

find public -- publicly available projections that were in the record in June of 1997 for what was expected when Kos was going -- would have been able to introduce its Niaspan product. The expectation at the time was that FDA approval would be obtained sometime in the summer of 1997 and the product would then be issued.

Niaspan was a -- like Niacor-SR was a sustained release niacin product, and in March of 1997, Kos went public, was very successful in its IPO, and as part of that IPO released projections and a description of their product and their expectations about the product. Those were then picked up in other media. Those projections are shown on that screen.

I have the highest one that I was able to find on the screen and the lowest one that I was able to find on the screen. So, as of the spring of 1997, the black lines on that chart represent what was in the public record about expectations for the first, second, third and in one case the fourth year sales that Kos would experience for its -- with its Niaspan product.

Q. And how did the Schering-Plough sales projections compare to the brokerage projections, high and low, for Kos in the first half of 1997?

A. Lows are illustrated by the blue line on the graph. You can see that they start out with first year

projections that are right in the middle of the range of projected sales for Kos, but in the second, third and in the fourth year, they are substantially lower than what was in the record, indicating the expectation of the -- of the market for the Niaspan product in the United States.

Q. And sir, you've compared Kos -- did you say that was a startup that had an IPO in '97?

A. Yes, it was. Kos was a startup, privately owned firm until March -- and I don't remember the exact date, but sometime in March of 1997, Kos went public through an IPO, became a public company. They were successful in getting FDA approval for Niaspan sometime in the summer, toward the end of July, of 1997. They did introduce the product in September of 1997, Niaspan.

Q. And sir, how would the Schering sales force, the detail force, compare to the Kos detail force in the first half of 1997?

A. Schering -- oh, Schering has a much, much broader -- certainly in 1997 had a much, much broader sales and marketing force than Kos did. Kos, being a startup, had very little in the way of detail force.

Q. Let me direct your attention to USX 1607, sir. Could you identify that? What is -- what's this

demonstrative?

A. Yes, that is an indication that -- it's an illustration of the point that I just made. In March of 1997, this is -- what the green line reflects is the market capitalization of Kos. In March of 1997, Kos went public. After its IPO, it was -- the market capitalization of the company was $300 million. By June of 1997, its stock had been increasing substantially, and so that by June of 1997, the company was -- its capitalization was $400 million. And by September of 1997, the stock had continued to rise, increasing to be somewhat in excess of $500 million.

Q. How many products did Kos have in the spring of 1997 that investors would be looking at if they were interested in buying Kos stock?

MR. EISENSTAT: Objection, Your Honor. How can this man testify as to what investors would be looking at if they were investing -- looking at investing in Kos? How does he know what could possibly be in the minds of investors?

MR. GIDLEY: Your Honor --

JUDGE CHAPPELL: I'll sustain it on lack of foundation.

MR. GIDLEY: I'll be happy to lay the foundation.

BY MR. GIDLEY:

Q. Sir, have you reviewed any of the contemporaneous brokerage reports that tracked and followed Kos Pharmaceuticals in the first half of 1997?

A. Yes.

Q. And have you reviewed those firms' expectations for Kos?

A. Yes, I have.

Q. And what were those expectations of future sales based on in the reports that you reviewed?

A. They were based on the sales of the Niaspan product.

Q. And that's a sustained release niacin product, sir?

A. Yes. Yes, it is.

Q. And was the company essentially viewed by investors as a single-product company at that time?

MR. EISENSTAT: Again, objection, Your Honor, as to how the company was viewed by investors at that time. That's outside the witness' scope of competence.

JUDGE CHAPPELL: I'll allow it. It -- I understand it's his opinion, his perspective.

THE WITNESS: Yes, according to the -- according to the records that I've seen, the expectation was that Niaspan would be the product on

which Kos would -- Kos' value was based.

BY MR. GIDLEY:

Q. Now, directing your attention to USX 1608, would you describe the chart that you've prepared that has been designated USX 1608, sir?

A. Yes, as I said, the reason for me going through this analysis was to look at the market and to look at the expectations of the market as they would relate to expectations for the value of Niacor, and it's pretty clear from the -- it is very clear from the record that both Schering-Plough and Upsher-Smith knew about Kos. Upsher knew that Kos was a product -- Kos' Niaspan product was a product that was similar to theirs.

Both of them thought that this product would be successful, and they both knew that the IPO was an indication of that -- that a niacin SR product, sustained release product, would be quite valuable. And therefore, I compared the valuations that were done by Schering-Plough and the settlement agreement, the amount of money that was transferred ultimately as a part of the settlement agreement, with the market capitalization for Niacor, which indicated the value indirectly of their Niaspan product in 1997.

Q. Sir, your -- SP's valuation legend appears next to two dots. Why are there two dots for

Schering-Plough's valuation?

A. Because in June of 1997, the final -- the most -- the most complete representation of Schering's estimate of the value of the Niacor license was reflected, as mentioned before, in a presentation to Schering-Plough's board, and in that presentation, the value of the Niacor opportunity was presented as a range, that -- I can't remember the precise number, I think it was $225 to $250 or $260 million. So, the lower point represents the low end of that range, and the higher point represents the higher end of that range.

Q. And how does that compare to the way stock market investors reflected in the stock price of Kos Pharmaceuticals reviewing Kos at that time?

A. Well, the results of the market decisions on the Kos stock are represented by the market capitalization. The sum of the supply and demand of the Kos stock in it shows that Kos was valued at that time at in excess of $400 million.

Q. I see at the bottom of the document, it says, "Payment to USL." What is that? Is that the up-front payment?

A. That is the sum of the up-front payments, the $60 million worth of payments, which, in fact, is a

total of less than $60 million in present value and expressed as of June of 1997, so it's roughly $54 million.

Q. Now --

A. And it's put in there in context to show the value of payments made under the settlement, the value that Schering was representing internally as -- of what the Niacor opportunity was, and it compares it with the market evidence that we have of what the market was valuing a similar product at in June of 1997.

Q. Just so we understand the comparison here, Schering-Plough's valuation would be for Niacor-SR, the sustained release niacin product, in non-NAFTA countries. Is that correct?

A. That's right.

Q. And Niaspan at this time was primarily a product where people were looking for future U.S. sales. Is that correct?

A. It was -- yes, it was entirely U.S. at that time.

Q. Now, does that difference mean that we can't compare the two valuations, or do you think they're comparable?

A. No, I do think -- I do think they're comparable. The size of the non-NAFTA pharmaceuticals

market is, if anything, larger than the U.S. market, and the Schering-Plough valuation was done explicitly knowing that the sales that were relevant to the future value of Niacor were going to be non-NAFTA sales based on their understanding of the European market and the Japanese market and other country markets that are outside the NAFTA agreement.

At the time, Kos had no public plans to go to other countries. Ultimately, sometime in 1998, I understand they announced that they would try to obtain foreign penetration, but they haven't to date been selling anywhere outside the United States, and the Schering expectation was very explicit, that they would have Niacor's sales starting in 1999 in the non-NAFTA area and that they would have a three-year head start over Kos.

That's an important consideration for them, that Kos would not be selling its Niacor product -- Niaspan product, I'm sorry, in the non-NAFTA area for three years.

Q. Now, let me set aside the Niacor-SR license that Upsher-Smith granted to Schering-Plough in June of 1997. You mentioned other products were licensed. Let me show you USX 1603. Have you analyzed the valuation of the other product licenses that are contained in the

June 1997 agreement?

A. Yes. These are summarized on this exhibit.

Q. And what have you done?

A. If you'll recall, there were six items listed. I've summarized that here and the -- and listed them slightly differently, but they are the products that, in addition to Niacor-SR, are licensed by Upsher-Smith to Schering as part of the license agreement.

Q. Now, what is the time period that the sales projections are based on for the $10.1 million figure that appears on 1603?

A. This was a five-year period. I did not go beyond five years. You'll recall that the Niacor projections were done for a ten-year period. These were done only for a five-year period.

Q. And this figure, 10.1, that's in millions?

A. Yes, it is.

Q. And the 10.1 is as of June of 1997. Is that correct?

A. Yes. It's analogous to the 100 million -- $110.8 million number that I mentioned before. What this analysis does, as did the other one, is it looked to expected revenues for a five-year period in the future and brings it back to a single number by discounting a single number back as of the date that

we're interested in, which is June 17th, 1997.

Q. So, this is another discounted cash flow valuation?

A. Exactly. It's a discounted cash flow for each one of the line items that you see there, the cholestyramine and pentoxifylline.

MR. EISENSTAT: Your Honor, I would like to object to the use of this demonstrative. I do not believe that we were presented with this by any of the underlying calculations that he's just -- the witness has just talked about prior to today's testimony or prior to his deposition. I don't believe we ever saw this until we got this demonstrative, and we have no idea how -- how it was calculated and no way to verify it.

JUDGE CHAPPELL: So, are you saying this is beyond the scope of the expert report provided to you?

MR. EISENSTAT: Yes, it was, Your Honor.

MR. GIDLEY: Your Honor, may I address that?

The expert report directly addressed the net present value of these products. The expert report included valuation information, and this was -- there was a similar chart to this that was part of his report in October and was available for deposition in December. There is, in fact, a footnote that gives a

larger number, and this is actually a smaller number, but there's a footnote that values these products. This was certainly available to complaint counsel at the time of the deposition.

MR. EISENSTAT: We had information that he -- about the present value, but it wasn't these numbers. It was a completely different -- as I recall, it was a completely different chart.

MR. GIDLEY: I think it's also the case, Your Honor, that the backup data for this presentation comes from Schering-Plough business records, and I can establish that. There's nothing novel about the fact that Dr. Kerr has valued the other five products. Complaint counsel may not like the testimony, they may not like the valuation, but they've had access to it.

MR. EISENSTAT: It's not about liking or disliking, Your Honor. It's an ability to check. The man just testified that he did a net present value. We've never seen that net present value calculation.

JUDGE CHAPPELL: I'm going to hold off ruling on your objection, Mr. Eisenstat, until you conduct your cross. As I've ruled all along in this trial, if you demonstrate to me that someone's trying to pull out an expert opinion for either side that wasn't provided, I will not regard it.

Proceed.

MR. EISENSTAT: Very well, Your Honor.

MR. GIDLEY: Thank you, Your Honor.

BY MR. GIDLEY:

Q. Sir, directing your attention to the footnote in USX 1603, there's mention there of production agreements. Do you see that?

A. Yes.

Q. And in your valuation work, have you sought to assign a particular dollar value to the six production agreements that were granted to Schering-Plough?

A. No, I did not assign a particular dollar value to them, though I recognize they are valuable.

Q. All right. And in fact, Dr. Bresnahan so testified, did he not, that they had positive value as of June 1997?

A. I believe he did.

Q. Directing your attention to USX 1604, could you describe for us the summary that's in USX 1604? It's at tab 21.

A. Yes, this summarizes the valuation that I performed for both Niacor and for the group of other products.

Q. All right. And taking the left-hand side, what's on the left-hand side of this exhibit?

A. The left-hand side reflects the present value as of June 17th, '97 of all of the payments that Schering-Plough would have been obligated to make to Upsher-Smith, attendant with the sales of the products that we've mentioned, the six products.

Q. Well, for instance, sir --

A. And the total is -- I'm sorry, the total is $91.4 million.

Q. I see where it says, "3 Upfront Royalty Payments: $51.7 million."

Why is that figure lower than the $54 million that Dr. Bresnahan was testifying about?

A. I believe Dr. Bresnahan testified using a 15 percent discount rate. If you'll recall, in my analysis of this set of licenses, I used a 25 percent discount rate for the Niacor discounting.

Q. So, the higher discount rate knocks down the number a little bit more?

A. The higher discount rate knocks the number down, that's right.

Q. And you're not saying this is the discount rate that Upsher-Smith used in 1997, are you?

A. No, I'm not.

Q. Their discount rate in 1997 was what approximately?

A. Eighteen percent, between 15 and 18 percent.

Q. All right. The other numbers, the Niacor-SR running royalties and the milestone payments, again, had those been reduced by the 25 percent discount factor?

A. Right. Those come directly from that calculation that was illustrated on the prior slide for the value of Niacor.

Q. And directing your attention to the right-hand column, there are two figures, Niacor-SR, 202, do you see that?

A. Yes.

Q. What is that?

A. Those two figures represent the income that Schering-Plough would have expected from sales of Niacor under the assumptions that we've already spoken about and the income that they would expect from the other products, again, under the assumptions that we spoke about earlier. So, the right-hand side shows that if Schering-Plough were to have gone forward with these licenses and been successful, as they expected, they would have generated for Schering-Plough $212.3 million worth of profitability over the period that we analyzed when expressed back in terms of June 1997 dollars. For that, they would have compensated

Upsher-Smith $91.4 million in present value terms.

Q. And the other five products there, that's your $10.1 million number, sir?

A. Yes, it's the one from the prior exhibit.

Q. And if we didn't have the $10.1 million number, we would be at $202 million for the right-hand side?

A. Yes, we would.

Q. All right, directing your attention to the next slide, USX 1605?

A. Yes.

Q. What's the conclusion you draw in this slide that you prepared?

A. That does the arithmetic. That shows the excess expected value that Schering would be -- would have been able to obtain had they been able to sell these products, $212 million, which comes from the prior page, minus the $91.4 million that they would have compensated Upsher-Smith under the license agreements, ends up with $120.9 as the expected value, the net expected value, of the licenses as of June 17th, 1997.

Q. And again, this is net of the up-front payments. Is that correct?

A. Yes. If you'll recall, on the prior page where I had the fees to Upsher-Smith itemized, one of those

items was the up-front payment. The other two were the running royalty and the milestone royalty.

Q. And it's also a net present value expressed as of June 1997?

A. Yes, it is.

Q. That's the $120 million -- $120.9 million?

A. Yes, it is.

MR. GIDLEY: Your Honor, we're at a natural point for a break if it please the Court.

JUDGE CHAPPELL: Okay, let's go ahead and take our mid-morning break here in early afternoon. We'll recess until 12:30.

(A brief recess was taken.)

JUDGE CHAPPELL: Mr. Gidley, you may proceed.

MR. GIDLEY: Good afternoon, Your Honor. I believe we have got an understanding on that objection earlier to the exhibit on the other five drugs.

MR. EISENSTAT: Yes, Your Honor, counsel for respondents were kind enough to point out where the numbers come from, and I withdraw my objection to the demonstrative number 20, USX 1603, and the testimony.

JUDGE CHAPPELL: Thank you, and thanks for working it out during the break.

MR. GIDLEY: Yes, Your Honor.

BY MR. GIDLEY:

Q. Dr. Kerr, earlier today you were testifying about your analysis, and you were talking about the assumption of 100 percent, i.e., that there was 100 percent chance that both Upsher-Smith and Schering-Plough would appeal in the patent infringement case. Do you recall that?

A. Yes. Yes, I do.

Q. And 100 percent is the number you used in your decision tree analysis. Is that correct?

A. Yes, I did.

Q. And sir, if I could go back to that slide for just one second, I want to clear one thing up for the record.

May I direct your attention to tab 10 of your binder, USX 1597, sir. Actually, we've got tab 9 up, and it's probably even better, sir. I show you USX 1596.

A. Yes.

Q. Average date of final resolution, February 2003.

A. Yes.

Q. We talked about that earlier today.

A. Yes.

Q. Now, in arriving at the average date of February 2003, sir, did you assume that the chance that

Upsher-Smith -- the chance that Upsher-Smith would appeal the underlying patent infringement case would be 100 percent?

A. Yes, I did.

Q. All right. And then later you said in a phrase that you stacked the deck in favor of Schering, and I just want to clarify this point.

Your calculation is based on the assumption that there's a 100 percent chance that Upsher would have appealed had they lost the patent infringement case. Is that correct?

A. That's right.

Q. All right. Now, if, in fact, due to any amount of -- any other circumstances Upsher-Smith did not appeal, how would that affect your February 2003 date?

A. It would have moved the February of 2003 date out.

Q. And when you say --

A. Because it would have increased the chances that Schering-Plough would have ultimately prevailed, because the -- if Upsher didn't appeal, there's no chance that they can get their loss at the District Court level reversed, only if they appeal can they do that, and given that I used the 100 percent, even though it's conservative, that affected the date in the

way I've just mentioned, which is to keep the February 2003 date in rather than a later date that would occur if I used less than 100 percent.

Q. And when you say move the date out, do you mean later in time?

A. Yes. Yes, move it out and expand the 17 months so that the amount of acceleration would have been larger.

Q. By the way, did you do any kind of sensitivity analysis on the results that you presented here? Have you looked at other scenarios?

A. Yes, I have.

Q. And generally, what bearing did that have on your opinion here?

A. Well, we -- as I mentioned before, the numbers here reflect an analysis, a path analysis, that allowed for 17 possible outcomes to the litigation. We also did versions of this that looked at 40 -- more than 40, more than 70 and, in fact, in one case over 100 different outcomes. We reduced that when we did the final production for simplicity's sake, but none of them had dates that would have been earlier than February 2003.

We also did an analysis -- did several different analyses using different percentages of

various of the inputs, and the results were not significantly different.

Q. Okay. Directing your attention to USX 1603, which appears at tab 20, you testified earlier that you used a five-year time horizon. Did you also look at a ten-year time horizon?

A. Yes, I did.

Q. And by including more sales, is that figure larger?

A. Yes, it would be.

Q. All right.

A. Approaching, as I recall, $17 million.

Q. And for the other five drugs, you've chosen the smaller number of $10 -- approximately $10 million. Is that correct?

A. Yes, $10.1 million.

Q. All right, sir. Let's move forward to tab 23, USX 1609, sir, Technology Sharing Agreements for Pharmaceutical Products. Could you describe this slide and what's being represented here?

A. Yes, that's an analysis that I did of a publicly available database which contains information on various kinds of technology-sharing agreements, including licenses and other more exotic kinds of arrangements for transferring intellectual property in

the pharmaceuticals industry. And the reason I did this was to -- was because we were dealing with a number of different pharmaceuticals products in this case, and I wanted to illustrate the point that as a product becomes closer to market, the intellectual property in that product tends to be much more valuable, because a pharmaceutical product -- pharmaceutical products of necessity have a long lead time of development.

They go through development, exploration stage, testing stage. They get into clinical trials, and they go through phase I, phase II, phase III clinical trials before getting to the FDA for approval, but from an economic perspective and from a market perspective, the importance of that long stream of development events is that as products get closer to market, they become more valued.

In this case, Niacor was in phase III, indicating that it was a more valuable product than an earlier product. The other products that were involved here were even beyond Niacor in their development. What this illustrates is that on average, the royalty that's paid for pharmaceuticals products increases as the products go from phase I, phase II, phase III, phase III being the closest one to the market, and the

average dollar amount of the license agreements, the technology-sharing agreements, also increases, not surprisingly.

As I recall, we had about 250 different licenses accounted for in this database. Different numbers reported royalty percentages than did dollar amounts, so there is not 250 in both of those calculations, but there's a significant number of licenses.

Q. All right. And what kinds of transactions were involved? Was it just licensing or were there other kinds of transactions involved in the database?

A. Oh, it wasn't just licensing agreements. That's why we call them technology-sharing agreements. There are -- it's -- it is rare, in fact, in the pharmaceuticals industry that you see a license that is just a license. Most intellectual property is transferred in more complex arrangements that amount to the same thing, but -- from an economic and market perspective but are different from the legal perspective.

They are called co-promotion programs, they are called joint ventures, they are equity investments that either in whole or in part transfer ownership, but they could all be reduced economically to essentially a

license agreement, and that's what is represented here. All of those kinds of transactions are represented in the population that we're looking at here.

Q. Is it fair to say based upon this database that there are a variety of structures and ways to structure the compensation or payment under a technology-sharing agreement for pharmaceutical products?

A. Oh, sure, sure, and they can be quite complex, similar to this case, where you have milestones, up-front payments, running royalties. You might also have equity payments. You may have, instead of payments that are just made for a royalty, regardless of the timing of the royalty, they may be tied to certain things. They may be treated as compensation for R&D. They may be -- they may be treated as an equity investment or a -- or a debt investment.

Q. In your view, is there anything sinister or unusual about large up-front royalty payments?

A. No, not at all. It's a form that is quite common.

Q. Let me direct your attention to USX 1610, and what is this exhibit? What's going on here?

A. This is information that I obtained when -- from the -- from a presentation made to the Licensing Executives Society by Dr. Medford, who's the president

of a company called AtheroGenics, earlier this year, and it -- it's the underlying source, I believe, of the economic phenomena that I illustrated on the prior slide. The reason that products get to be more valuable and the intellectual property underlying those products get to be more valuable as the product comes closer to market is that in pharmaceuticals, more than in most other industries, there is a substantial risk that any particular product in the pipeline at any time won't get into the market.

So, there's a real premium to being close to market, because as you get closer to market, you've crossed so many of what are very difficult hurdles, and what that slide shows is an estimate of how many products at each stage get to market compared to the number that come in, and that's -- so, for example, for every thousand products that pass the discovery stage, one gets to market. For every hundred products that go to the next level, which is the toxicology stage, only one out of a hundred get to market. Phase I products, ten out of -- one out of every ten phase I products get to market, and so on.

And when you get to the phase III, which is the last step for FDA approval, you're still at a point where only one out of two, 50 percent of the products

that get to phase III get to the market.

Q. Are there a lot of dry holes in pharmaceutical innovation, sir?

A. Sure, and that's an illustration -- illustrated by this chart. Somebody has to pay to develop the 999 discovery products that don't get to market. For the phase III products, you've invested a huge amount of money typically and a lot of time and resources to get each product to market. Only one of them actually gets to market. The other one still has to be paid for.

Q. Can the --

A. That's the dry hole.

Q. -- executives in these companies predict with perfection which drugs will succeed and which will fail?

A. Some do a better job of it than others, but in general, no, they can't predict.

Q. Let me direct your attention, sir, to tab 27, USX 1614. It's a slide entitled Pharmaceutical Companies Interested in Niacor-SR.

A. Yes, I have it.

Q. And sir, what is this slide?

A. This was the other piece of the analysis I mentioned before. In addition to doing the quantitative analysis of the value of Niacor, I looked

at the market to put that quantitative analysis that I did in context. The prior one -- the prior market analysis, if you will, dealt with Kos and the Niaspan product.

In addition, though, I determined from the record fairly early on that Upsher-Smith had been involved in an effort to gather intelligence on the market for the intellectual property that it had, and in this case for Niacor. They had attempted to obtain a license for Niacor product -- for the Niacor product that would have generated income for them outside of the United States.

Q. At this point in time, the first half of 1997, did Upsher-Smith have an overseas sales force?

A. No, it didn't.

Q. Did it have any sales presence in Europe, to your knowledge?

A. No, no, it didn't.

Q. And sir, these companies, Pierre Fabre, Dr. Esteve, Lacer, et cetera, where are these companies based?

A. Well, all of them are -- have operations in Europe. Some of them are not based there but operate there. Pfizer, for example, and Searle are, of course, multinationals, as are -- as, in fact, are the

Europeans multinationals, but each of them has a home base in -- Fabre is in France, Esteve is in Spain, Lacer is in Spain. The one down at the bottom there is identified as being in Bombay, India and, in fact, is. Nycomed is Greek.

Q. And sir, what's your understanding of who was conducting this marketing effort on behalf of Upsher-Smith in the first half of 1997?

A. At that point, I understand that the primary person was Ms. Vickie O'Neill.

Q. Okay. And had the company used anyone outside of Upsher-Smith?

A. Yes, at the end of 1996, I believe we've seen in the record reference to the hiring of a consultancy in -- based in the UK named Moreton. Mr. Pettit from Moreton was the consultant that they used.

Q. And the column -- I'm sorry.

The column that says, "Secrecy Agreement," what does that refer to, those dates in that column?

A. The dates in that column refer to the dates on which the companies shown signed an agreement with Upsher-Smith to share information, to share confidential information, on the Niacor product so that they could evaluate the product.

Q. So, how many companies had signed secrecy

agreements according to this slide?

A. Seven.

Q. And the column that says, "Documented Interest," how many companies did you conclude had documented interest in Niacor-SR?

A. Well, there are eight companies with entries on that -- in that column. The other two clearly had documented interest as well -- had interest as well, but I didn't have a document. This refers literally to a document, where I was able to find a document in the record that indicated an interest. In the case of the other two, there's information in the record that indicates an interest, although it's not a document.

Q. Now, "Meeting with USL," what does that refer to, the final column?

A. That's literally what it is. This is evidence in the record that those parties indicated with an indication in that column actually met with Upsher-Smith to discuss the prospects of licensing Niacor.

Q. Now, this sales effort, this marketing effort of Niacor-SR on behalf of Upsher-Smith was primarily focused in Europe. Is that correct?

A. Yes, it was.

Q. Now, Fournier, the company that's got this date

of May 8, 1997, what arrangement were they interested in?

A. Fournier was a -- is a French company, a large French company with operations in a number of other markets as well, and the meeting that is referred to as of May 8th, 1997 dealt not with the market outside of NAFTA but dealt with the prospect of Fournier and Upsher-Smith engaging in a joint venture to distribute the Niacor product in the United States when it became available.

Q. Sir, I direct your attention to Pierre Fabre.

A. Yes.

Q. What's your understanding of the discussions that took place between Upsher-Smith and Pierre Fabre as to a Niacor-SR license in general terms?

A. Pierre Fabre had, as is indicated on the table, had signed a secrecy agreement and indicated an interest and met with Ms. O'Neill and other Upsher-Smith people in Europe, and the date there is June 3rd, 1997, in Paris, as I understand it, and they were -- they had expressed an interest. They talked about the market and were -- had an active interest as of that time.

Q. Did they express any dollar figures in that meeting?

MR. EISENSTAT: Objection, Your Honor, as to the hearsay aspect of this.

MR. GIDLEY: Your Honor, if I may, an expert witness can rely on hearsay. As have all the other experts in this case, Dr. Kerr has reviewed the record, and obviously we're not saying he's in the room. We're talking about what informed his valuation here.

MR. EISENSTAT: And Your Honor, as long as it's not coming in for the truth of the matter stated, we have no objection. If it was just the basis for his opinion, we have no objection. If they're offering this testimony for the truth of those statements, then we would object.

MR. GIDLEY: Your Honor, we offer it for his understanding. We're not offering it for actually what was said. Dr. Kerr was not in the room.

MR. EISENSTAT: No objection, Your Honor.

JUDGE CHAPPELL: Okay, so it's withdrawn, and that's the way I understand this also. I'm assuming that Mr. Gidley hasn't brought this gentleman here to tell me what was said in a room half a world away. I'm assuming he's explaining the basis of the opinion.

MR. EISENSTAT: And as long as -- with that understanding, Your Honor, we have no objection.

JUDGE CHAPPELL: Thank you.

You may proceed.

BY MR. GIDLEY:

Q. Dr. Kerr, do you have an understanding about whether or not Pierre Fabre was talking about any dollar figures for a Niacor-SR license based on your review of the record?

A. Yes. Yes, I reviewed in particular a memo that was prepared by Ms. O'Neill upon her return that discussed her understanding of the interest that the other parties had had, and in one of those -- in that memo, one of the companies mentioned was Pierre Fabre. The -- as I recall the memo, it referred to a $50 million figure as being something that Fabre considered to be too large, but it was a $50 million figure proposed for them for a similar product from a similar company, although an IPO, which I believe Ms. O'Neill testified she took to be Kos as the unnamed company.

Q. Ms. O'Neill testified by deposition?

A. In deposition, yes.

Q. And you reviewed her deposition, sir?

A. Yes.

Q. Let me direct your attention to the boxes by Nycomed Hellas and Kopran, where under Documented Interest, it says, "Post June 17" and "June 30."

A. Yes.

Q. Now, those expressions of interest, would they have been acted on by Upsher-Smith after June 17th, 1997?

A. No. No, they wouldn't, because they by that time had signed the agreement with Schering which gave the rights to Niacor for outside of NAFTA. In fact, a number of the companies higher up in the list, too, Dr. Esteve comes to mind, I believe Servier was another, and Searle, all were -- all had contacts with Upsher-Smith after June 17th, and I believe it's true that the consistent response from Upsher-Smith to any correspondence related to Niacor at that point was we've already signed an agreement outside the United States with another person and that that person has the right to sublet -- sublease -- I mean sublicense the product, and they referred them on to Schering-Plough.

Q. Sir, are you familiar with an allegation made in this case that Upsher-Smith was paid to delay its entry into the selling of Klor Con M20? Are you aware of that allegation?

A. Yes.

Q. And sir, have you made any conclusion about whether or not Upsher-Smith was, in fact, paid to delay its entry into the selling of Klor Con M20?

A. Yes.

Q. And what is that conclusion?

A. Well, there are two pieces of it. I mean, the first we've already discussed. I've analyzed the settlement portion of this agreement and determined that there's no evidence at all that there was a delay.

Secondly, looking at the payment side, it's clear to me that the royalty agreement, which contained up-front payments, up-front royalty payments, milestone payments and license fees, were reasonable values to be considered against the intellectual property that was transferred and that it doesn't seem to be an excess payment that might carry over onto the settlement side.

Q. And sir, have you made any conclusion about whether there was actual delay in this case, whether Upsher-Smith could have gotten a date from Schering-Plough earlier than September 1, 2001?

A. I've seen no indication that they could have. Just the reverse, the testimony has been consideration --

Q. Keep your voice up --

A. I'm sorry, that there was no consideration of any time prior to September 1st, 2001.

Q. All right, sir, I want to talk to you briefly about the concept of hindsight. Is that a topic you talked about in your report?

A. Yes. Yes, it is.

Q. And why did you get into the topic of hindsight in your report in this case, sir?

A. The -- the topic arose in early -- early on in the case, because it appeared to me that there was an allegation that the fact that the licensed products, the products licensed to Upsher-Smith -- from Upsher-Smith to Schering-Plough in large part did not result in the kind of sales that were expected, indicated in the record as of June of 1917 -- I'm sorry, 1997, June 17th, and for that reason, it was alleged that the -- that the licenses didn't amount to a value equal to the $60 million worth of up-front payments that were involved, and I think that that's an -- if that was the allegation, it would be an inappropriate one, because the proper way to express the value, as I've mentioned before, is as of June 1997, not taking into account the subsequent success or failure of the licenses.

Licenses in the pharmaceutical industry have a great deal of value regardless of whether the product is on the market, whether the product is going to get to the market, because nobody knows whether the product's going to get to the market. Intellectual property is bought and sold all the time in the

pharmaceutical industry, and it has to be to properly run the industry, transferring intellectual property back and forth between parties for consideration, and as we've seen in the chart that we were discussing a few minutes ago, even products that are so close to the market, as a phase III product, only 50 percent of them actually get to the market.

So, the vast majority of products that are contained in license agreements that are transferred among the members of the pharmaceutical industry, the developers and the marketers, don't ever generate any ultimate sales but have significant value.

Q. Is there an episode from the negotiations between Upsher and Schering-Plough that you used to illustrate the fallacy of hindsight in this case?

A. Well, one that I had mentioned I believe in my report shows that the parties to this case were negotiating back in 1997, and Upsher-Smith was offering a list of products to Schering-Plough to evaluate for the -- for purposes of the license, and one product, the product that turns out to have been the most successful of the products offered by Upsher-Smith to Schering, was a product called Pacerone, and that was a product that Schering opted not to take a license on.

Had the product been taken, the license -- the

value of the products to Schering-Plough would be much greater today, because, in fact, Pacerone was launched subsequently by Upsher-Smith and became its most successful product in 1998 and 1999.

Q. Can you give the Court an idea of the sales in 1998 and 1999 of Pacerone by Upsher-Smith?

A. In 1998, the sale -- the launch year, I believe the sales were about $36 million in the United States.

Q. All right. And have the sales remained strong?

A. They have. They've come down a bit from that, but they are still strong.

Q. And sir, I show you USX 843.

A. Yes.

Q. And is that, in fact, an advertisement for Pacerone?

A. Yes, that's the product that Upsher-Smith is now selling and selling successfully that was rejected by Schering-Plough during the negotiations in 1997.

Q. And the common name for Pacerone is amiodarone. Is that correct?

A. Yes, Pacerone is a variety of amiodarone and a brand of amiodarone.

Q. So, using hindsight, did Schering-Plough choose wisely or poorly in rejecting Pacerone, using hindsight?

A. Well, if you are entitled to use hindsight, you can say it was not wise for them to have rejected Pacerone, but, of course, back in 1997, I'm sure they had a very good reason for doing it. They looked at the products and chose the ones that they thought were most likely to be successful and that they could commercialize best for one reason or another, and I don't know the reason, but for one reason or another, they rejected Pacerone, and it turns out that Pacerone, of the products that were under consideration, was the one that has become the most successful.

Q. Let's use some more hindsight. Let's talk about Niaspan, Kos' product. How has Kos' product fared in the marketplace?

A. Kos' product has had a spotty history.

Q. How has it done in terms of sales volume? Has it ramped over time?

A. It has -- it has -- it is now doing quite well, but in 1997, when the product was actually introduced, it stumbled badly. It was introduced in the summer of 1997, by -- sometime in September I think was the official introduction date. It didn't come anywhere near the expected sales levels.

As a result, Kos' stock plummeted. The stock -- the sales of Pacerone -- of Niaspan continued

to lag through 1998 and 1999, but they grew. They grew little by little as Kos got their marketing and distribution out of the way, and in the most recent year, Niaspan is now hitting product sales levels that are -- that were close to what was expected of it back in 1997, but it's been a long struggle.

In the most recent year, I understand they have sold in excess of $100 -- probably $110 million worth of product in the United States.

Q. Let me show you -- let's go back to tab 18 for one minute, USX 1607, sir. That's the Kos stock price chart.

A. Yes.

Q. Does that illustrate what you were describing a minute ago, when you get there?

A. It does. Did you say 1607? Yes.

Q. Tab 18.

A. Yes. Yes, that does illustrate the -- that does illustrate that phenomena. As I mentioned before, the IPO occurred with great fanfare. The industry loved Kos. The investment community loved Kos. The product continued -- the market -- the stock market continued to value Kos very highly as the expectations grew that Niaspan would be a successful product.

In September of '97, the launch occurred. The

launch caused the price to fall, and through 1998, Kos' stock went in the other direction, and its market capitalization went in the other direction. What was valued by the market as a $400 million company in June of 1997, by June of 1998 was -- had a market capitalization of less than half that because of the inability of the market to use hindsight. They didn't know that the Niaspan sales were going to be as poor as they were initially.

Q. Okay. And sir, directing your attention to tab 26, USX 1613, is that your understanding generally of the sales trends of Niaspan in recent years?

A. Yes, those are -- that exhibit reflects the sales of Niaspan in 1999, 2000 and 2001, and as you see, in 19 -- even three years after its introduction in 1999, sales were only $37 million, and it was expected to have been at that point -- back in 1997 when the -- prior to this entry, they were expecting sales in excess of -- certainly in excess of 100, probably close to $200 million by 1999, and it was only hitting $30 million-odd sales.

But subsequently, as we said, it's caught up. It's caught on. Niaspan is now a successful product. In 2000, it was in the top 500 worldwide of pharmaceuticals products. The entity that does the

ranking of the top 500 products hasn't issued its ranking for 2001 yet, but with $100 million in sales, it's certainly going to be up in the 200 -- in the 200s rather than the top 400.

Q. Let's go on to a new topic, tab 28, I show you CX 348. Do you see that?

A. Yes.

Q. What is CX 348?

A. Excuse me, CX 348 is the agreement between Schering and Upsher-Smith. It's a -- it includes an attachment, Exhibit A -- Exhibit A, which memorializes the agreement.

Q. Sir, I just want to show you some language complaint counsel has used, and I preface this question with the fact that you're obviously not a lawyer. I want to just confront you with some language and see if it changes your opinion in any way.

Complaint counsel have focused on this introductory language in paragraph 11 at page 3188, and they like to focus on the fact that it references paragraphs 1 through 10 above. Does this document in any way change your opinion about whether or not there was a payment for delay in this case?

A. No, it doesn't.

Q. Why not?

A. The payments that are listed in paragraph 11 are the payments that I described to you previously. This is, in fact, the source of my information on those payments. There are four payments -- four types of payments involved. Up-front royalties in paragraph (i) of $28 million, another up-front royalty, $20 million, paragraph (ii). The third was an up-front royalty of $12 million. Then it describes milestone payments, royalties, a different kind of royalties. And finally, it describes, in paragraph (v) on the next page, running royalties.

All of those royalties are referred back to the SP Licensee, the SP Licensee will pay these royalties, and SP is the licensee on the four products that are described in here, the Klor Con products, you know, the several different dosage forms of Klor Con, the Prevalite, pentoxifylline and the Niacor.

Q. The license agreements and supply agreements we've been talking about, are those found in paragraphs 7 through 10 on pages 3187 and 88?

A. Yes, and paragraph 7 is where the discussion of those licenses is first introduced and SP Licensee is described, and it describes the licenses I've just mentioned, Klor Con, Prevalite and the others.

Q. Let me show you, if I could, tab 29, sir, USX

1615. This will be back on the screen in a second. Sir. What we've done is we've reproduced or blown up the first two sentences of paragraph 3 of Exhibit A from the June 17, 1997 agreement, CX 348.

Have you reviewed this language before?

A. Yes, I have. It's, as you say, straight out of the agreement.

Q. Have you seen language like this before in settlement agreements involving intellectual property?

A. Oh, sure. Sure, it's the kind of language you need to have in a patent settlement.

Q. And why do you say that it's the kind of language you need to have in a patent infringement settlement agreement?

A. Well, if you're going to end a settlement -- if you're going to arrive at a settlement and end the patent litigation, it's essential to describe what it is that the parties can and can't do.

Q. Sir, have you reviewed the drafting history of this provision at all?

A. I'm familiar with -- I can't say I'm familiar with the drafting, but I'm familiar with the way that the discussions went and what was being proposed by the parties at different times.

Q. You mentioned earlier today Klor Con M10, and I

see that that's mentioned in the second sentence. What's the significance you make of the second sentence with reference to Klor Con M10?

A. Well, I think I mentioned earlier, that's one of the aspects of this that I -- of this settlement that I think is pro-competitive. The underlying litigation that was set to go to trial in June of 1997 dealt only with Schering's patent on the '743 and Upsher's attempt to market its Klor Con M20. In fact, Upsher-Smith had plans to introduce both a 10 and 20 version, a 20 mEq and a 10 mEq version of Klor Con M, but the litigation was prompted by the filing of an ANDA, the abbreviated new drug approval, for M20 that was accepted some years earlier, and therefore, the M10 was not included in that underlying litigation.

However, subsequently, Upsher-Smith would have filed an ANDA, an A-D-N-A, for M10, been obligated, as any ANDA filer is, to notify the patent owner that they intended to bring a product to market, and would have been likely faced with another lawsuit, and that would have prevented M10 from coming in. So, this settlement agreement essentially allowed both of those products to come in. It not only ended the litigation that was in existence for the M20, it eliminated the prospect that in order to get the M10 to market, Upsher would have

had to fight another lawsuit.

Q. Now, sir, directing your attention back to the first sentence, sir, why is it that parties use language like this in general in intellectual property settlement agreements?

A. Well, as I mentioned, in order to reach a settlement, it's necessary to establish what's prohibited and what's permitted under the settlement, and the -- and if -- if an agreement like this -- if language like this were not in the agreement, it wouldn't say what to do.

Klor Con M20, for example, is a potassium chloride product, and it is a sustained release microencapsulated potassium chloride tablet, in particular, and that's the -- that phrase describes what was covered in the patent. If that phrase --

MR. EISENSTAT: Objection, Your Honor, with respect to this witness testifying as to what was covered in the patent. We have heard many days of testimony from patent experts who can't agree amongst themselves as to what was covered in the patent, and this witness has testified that he has no special skill or understanding with respect to microencapsulation or the coatings for capsules. So, this is clearly beyond his area of expertise.

MR. GIDLEY: Your Honor, the question is, why do parties use general language in addition to describing the product name, and Dr. Kerr has experience in counseling people in connection with intellectual property settlements. He's clearly not a lawyer, but he is certainly capable, as capable as Dr. Bresnahan and should be given the weight of Dr. Bresnahan's testimony, of looking at the agreement and drawing the kinds of economic inferences that an economist or an industrial organization economist would draw, and, in fact, we would submit he's actually more experienced, because unlike Dr. Bresnahan, he's looked at settlement agreements outside of this case.

JUDGE CHAPPELL: The objection is sustained to the extent the witness is purporting to give me a pharmaceutical or medical opinion about the equivalence of these two drugs. I'm allowing this witness to introduce the data and assumptions underlying his opinion, which you have the right to test on cross exam.

Proceed.

MR. GIDLEY: Thank you, Your Honor.

BY MR. GIDLEY:

Q. But in general, sir, is it the case that this kind of language in paragraph 1, the first sentence, is

typical in patent infringement settlement agreements in your experience?

A. Yes, it is.

Q. All right. And do you find that an anti-competitive feature of patent infringement settlement agreements?

A. No, no, not at all. It is -- but it is an essential feature in many patent agreements. The reason for that is that in order to end the litigation, you have to limit the ability of the potential infringer to go back and put out another product that infringes. You have to say what people are entitled to do and what they're not entitled to do.

It's a particularly important issue because of what is known in patent law as the doctrine of equivalents, and from an economic perspective, two products can be very similar and, in fact, in pharmaceuticals, even worse, because not only do they have to be similar from an economic perspective, but in order for a generic to be accepted by the FDA as a generic, it has to be what's called bioequivalent, which means that the generic -- the whole trick in bringing a generic product to market is to make it as similar as you can to the branded product.

That means that you're running the risk of

infringing the patent, and so you're on the one hand attempting to bring your product to market by making it bioequivalent, by getting the generic status, but you have to do that in a way that avoids the patent. The patent then -- the patentee then sues, and even though you might not literally be infringing the patent, you're running very close to it by trying to be bioequivalent, and -- whereas something like a literal infringement might be a certain percentage of a particular active ingredient, say 60 percent is required under the patent literally. Is 59 equivalent? Is a product that has 58 equivalent? Is a product that has 57 equivalent?

I mean, the point is that if you're involved in patent litigation, most of the time the patent owner thinks that the product is infringing, and most of the time the patent infringer thinks that the patent is -- that the product does not infringe. There's debate over what's infringing and what's not.

Q. I see.

JUDGE CHAPPELL: And based on that answer and related to the previous objection, I'm not accepting an opinion from this witness on what would or would not infringe a patent, as I maybe didn't make clear. It's something that we need to know in support of his

opinion what he thought the patent allowed or didn't allow, so I'm allowing that for this -- for this purpose.

You may proceed.

MR. GIDLEY: Thank you, Your Honor.

BY MR. GIDLEY:

Q. Let me direct your attention to a new topic and direct your attention to tabs 30 and 31, USX 809 and USX 810. Now, earlier today we were talking about a 25 percent discount rate applied to the three up-front payments. What do we have in USX 809 and 810?

A. 809 and 810 also relate to the three up-front royalty payments. Again, on the top line on both of the exhibits, you see the $28 million that was due in 1997, the $20 million in -- on the anniversary date of the settlement and the $12 million in 1999, and what these show is that by -- in order to express the value of the up-front payments to Upsher-Smith as of 1997, it's essential to discount, as we've done before, and to express them in terms of a single number as of June 1997.

The first of the two exhibits does that discounting at a 15 percent discount rate. The second does it at an 18 percent discount rate. And using the 15 percent discount rate, the value as of June 1997 is

$54,470,000, and as of 1997, June 17th, using an 18 percent discount rate, the present value is $53.57 million.

Q. I show you CX 283, sir, and is this a document that you've had occasion to review?

A. Yes, it is.

Q. And does this document in any way change your opinion about whether or not there was a payment for value in this case?

Oh, I'm sorry, Your Honor, this document is in camera, so before we flash it, we need to make sure that we can go in camera, Your Honor.

JUDGE CHAPPELL: Okay, and have you attempted to have all the in camera questions in one portion of your direct?

MR. GIDLEY: I believe so. Let me check with Mr. Malik.

MS. SHORES: Hang on one second, Your Honor.

MR. GIDLEY: Excuse me, Your Honor.

(Counsel conferring.)

MR. GIDLEY: It's a Schering document, Your Honor, so we just need to check for a second.

JUDGE CHAPPELL: Okay, and again, I would advise the attorneys, when you're preparing your direct or cross, please attempt to put the in camera issues

into one place so that we don't have to run the public in and out of the courtroom. Thank you.

MR. GIDLEY: I do have several other in camera exhibits which are clearly in camera, and I could do that part of the exam at this time.

All right, but this document is not in camera, so why don't we go ahead and proceed.

JUDGE CHAPPELL: So, the public is invited to remain. Thank you.

MR. GIDLEY: Thank you. We're on a short hair trigger on in camera.

JUDGE CHAPPELL: As we should be, Mr. Gidley.

BY MR. GIDLEY:

Q. Dr. Kerr, I want to direct your attention now to tab 32, CX 283, which we can now display.

A. Yes, I have it.

Q. Sir, does this change your opinion about whether or not there was a payment for delay in this case?

A. Yes, this was an interesting piece of the record that I reviewed, and it was very interestingly related to the valuation.

Q. And why does it not change your opinion?

A. It doesn't change my opinion because it shows that the -- if you -- if I call your attention to the

options at the bottom of that page, and this is a record that shows the -- that Schering was considering several different options for the settlement.

The fourth one apparently is the one they have taken, and that is, if I could read from it, "Review UPS portfolio and purchase pipeline products or in-line portfolio for SGP to promote." Then on the next line, there is a -- it says, "Estimated value," and unlike the other options, where Schering was apparently able to assign a value to the settlement agreement, there's the statement that the value of this depends on the products purchased and indicated to me that Schering was paying attention to the list of products that was being offered to them by Upsher and attempting to establish a value for those products.

As I mentioned before, the list was longer than the list that was ultimately settled upon. They looked at Niacor, they looked at pentoxifylline, Prevalite and the others, and they looked at Pacerone and opted not to take it. Apparently they didn't know what the value of the license was going to be and wouldn't have known until they went into the type of analysis that I mentioned before where they looked through and placed a value on each of the licenses, and that's reproduced on the second page, too, where they do the comparison of

the different options.

There's a large arrow that says, "TBD," to be determined, presumably based on the value of the intellectual property that was going to be transferred from Upsher-Smith to Schering.

Q. Sir, I show you CX 338, which is at tab 33 of your witness book.

A. Yes.

Q. Now, does this document give you any pause or concern as to whether or not there was a bona fide agreement in June of 1997 for value in your opinion?

A. No, it doesn't at all. This is, in fact, one of the documents that I referred to before that is -- that includes information that I -- upon which I relied in doing my own valuation.

Q. And sir, could you just point out which pages are ones that you relied upon explicitly in your quantitative analysis and valuation?

A. The quantitative information -- there are two. There's a paragraph on the page that has a number 271 at the end of it, which discusses the other products, the other products being the licensed products that were selected other than Niacor, and information in that paragraph is -- is an indication of what Schering's expectations were regarding the revenues and

costs and therefore the profits that would be expected from the other products. And then there are a few other paragraphs right after that describing a few of the individual products.

And then if you look at Table I, which is on page -- the Bates number ends at page 273, that shows the projections for Niacor-SR worldwide. The page following that shows the earnings impact from those sales, which is the page that ends in the Bates number 274.

And then finally, the last quantitative point is on page 275, which is headed the Financial Impact of Niacor-SR, and if you will recall on an earlier slide I listed the value that Schering-Plough applied to Niacor-SR. That comes from this page in the lower left-hand corner, you'll see that Schering-Plough's -- the economic value assigned to Niacor by Schering-Plough was between $225 and $265 million.

Q. Dr. Kerr, may I direct your attention back to page 273?

A. Yes.

Q. And the heading is Niacor-SR Worldwide Sales. Do you see that? Table I.

A. Yes.

Q. Now, is it literally worldwide sales or does it

exclude certain regions?

A. It's except U.S., Canada and Mexico. It does not include the sales in the NAFTA countries. They were not included in the license.

Q. Thank you, Dr. Kerr.

Dr. Kerr, now you've conducted your own independent valuation of the consideration exchanged in the June 1997 agreement. Is that correct?

A. Yes.

Q. And that's part of the basis for your opinion of why there was no payment for delay?

A. Yes.

Q. Do you draw any inference from the fact that the agreement had to be presented to the Schering-Plough board of directors before it became effective?

A. Well, that's important in the sense that it is not -- it indicates the seriousness with which Schering was treating the agreements and the importance of the agreement to Schering.

Q. I want to go to a new topic, sir, if we could go to tab 34, which I think we can put this up on the screen, USX 1616. I want to just ask you one or two questions about this slide.

A. Sure.

Q. Now, sir, this business about reverse payments, is there a long history of economics to draw upon? Is there a well-trod path of economics that guides us here?

A. Well, there's a -- there is, of course, a long history of economics dealing with competitive effects. I know of no particular piece of economics, either in theory or in practice, that deals with agreements such as this one. It requires a great deal of effort to apply economic theory in the analysis of competitive effects to any specific agreement, and these agreements are relatively new, and in large part the underlying dispute here flows from what's known as the Hatch-Waxman Act, as I mentioned before, the way that generic products are able to be approved and come to market. And so it requires a significant effort to try to apply economic theory and economic methodologies to the analysis of the competitive effects in this case. It's certainly not a superficial exercise.

Q. From the standpoint of economic principles, I want to ask you a few questions. This first statement, "This case does not challenge the settlement of patent disputes by an agreement on a date of entry, standing alone," let's take that half of the sentence.

A. Yes.

Q. All right. If two competitors agreed that one would not enter a market and there were no other facts, is there a body of economic thought that addresses that stark scenario?

A. If two competitors agree not to enter -- that one would not enter the market, is that --

Q. Right, and there's no patent, there's no lawsuit.

A. Yes, yes, there is. I mean, in general, that is an agreement that would be viewed very -- to be very likely to be anti-competitive, almost per se -- I don't want to use "per se," that's a legal definition rather than an economic one, but one which economic theory would pretty easily condemn.

Q. But does the introduction of the patent at a patent infringement lawsuit change the economic analysis in your view?

A. Oh, yes, it certainly does. The rights that a patent owner has to practice the patent, the technology to sell the product under the patent, provide the patentee with the ability to control the use of that patent during the life of its product.

MR. EISENSTAT: Objection, Your Honor, to the extent we're now getting into what it sounds like are legal opinions with respect to what rights, what legal

rights, a patent holder has, and again, I don't think this witness is qualified to render legal opinions with respect to patent rights.

MR. GIDLEY: Your Honor, we would never offer Dr. Kerr for a legal opinion. We're asking Dr. Kerr what should or should not be anti-competitive in the view of economists, and this is an inquiry which Dr. Addanki and Dr. Bresnahan have commented on. I want to briefly cover what should be considered anti-competitive or pro-competitive by this economist. That's the basis of my questions.

JUDGE CHAPPELL: Well, as I have been doing, I will treat your objection as a motion for limited admissibility under Federal Rule 105, and I'm allowing this witness to give me the information that he used in coming up with his opinions, but I'm not accepting legal opinions from this witness.

BY MR. GIDLEY:

Q. Dr. Kerr, in the instance of a patent infringement lawsuit where there was a settlement agreement and it's a one-dimension settlement agreement, there's no side license, would the agreement on a date of entry by itself be anti-competitive in your view?

A. No, certainly not from an economic perspective.

Q. Why not, sir?

A. Well, because it goes back to the early part of my testimony. The settlement needs to be compared with the outcome of the litigation before you can determine whether the settlement is pro or anti-competitive. So, on its face, it can't be considered anti-competitive.

Q. Let's take the second half of the sentence.

From the standpoint of economics, is a multidimensional settlement which includes side deals at fair market value, is that something that you would find anti-competitive?

A. Certainly not, no.

Q. In your experience, do patent infringement settlements often have multidimensional aspects?

A. Virtually all -- any type of agreement having to do with intellectual property has side deals, and if you -- meaning that there are unrelated intellectual property rights moving in both directions between parties. It's not only patent settlements but other kinds of patent -- other kinds of agreements having to do with intellectual property always have what are known as side deals.

It's often impossible to say which is the side and which is the main deal, and there's no way that simply by finding the presence of a side deal that one

could conclude that from an economic perspective a particular agreement is anti-competitive.

Q. Is a mutual exchange of releases or cross-licensing arrangements, are those common features in patent infringement settlement agreements?

A. Yes, they are.

Q. And value would be going in both directions under those arrangements typically in your economic view?

A. Absolutely.

MR. GIDLEY: Your Honor, I think this is an appropriate time to do the in camera exhibits, if it please the Court.

JUDGE CHAPPELL: Okay, at this time I'll have to ask the public to leave the courtroom. We're going into in camera session. You'll be notified when the public is allowed back into the courtroom. Thank you.

(The in camera testimony continued in Volume 26, Part 2, Pages 6460 through 6468, then resumed as follows.)

JUDGE CHAPPELL: Mr. Gidley, how much direct do you have remaining?

MR. GIDLEY: We're under 15 minutes at this point, Your Honor.

JUDGE CHAPPELL: Thank you. You may proceed.

Thank you, Mr. Chase.

BY MR. GIDLEY:

Q. Dr. Kerr, I'd like to understand a little more about your opinion about the overall competitive consequences of the June 17, 1997 agreement.

Have you formed an on balance assessment of whether the agreement was pro or anti-competitive?

A. Yes.

Q. And what is that opinion?

A. My opinion is that the agreement was pro-competitive and that it had pro-competitive effects.

Q. Okay. Can you outline for the Court briefly some of the pro-competitive effects of the agreement?

A. Well, the first and most important of the pro-competitive effects is that by my analysis, the settlement portion of the agreement actually accelerated the entry of Upsher-Smith over what would have been likely had the -- had the agreement not been signed.

In addition, the settlement of the lawsuit had beneficial effects in the sense that it prevented the need for spending the money that would have been required to take the case through trial, through appeals and so forth.

Also, the -- there are significant values in allowing people to exercise their intellectual property rights. There are benefits that come through the encouragement of innovation, and that affected both the intellectual property rights that Schering had for the Klor Con products but also the intellectual property rights that Upsher transferred to Schering on the other licenses.

So, all of those things in general -- I mean, in total lead me to conclude that this agreement was pro-competitive.

Q. Did Upsher-Smith earn a return on its R&D investment by virtue of the June 1997 agreement?

A. Yes, it did.

Q. Do you know approximately what that R&D investment was in the products that were licensed?

A. Well, I do know that Niacor, by the time they entered into the license agreement for Niacor, they had spent in excess of $12 million developing Niacor. Subsequent -- there was subsequent additional costs expended after June of 1997. There were also costs related to Prevalite and the other products that were included in the license, and I don't know precisely what those were, but certainly there were costs that they used to do -- that they expended to develop these

products, and those were -- they had a return on those as well.

Q. You mentioned a moment ago litigation expenses. Why would saving litigation expenses be pro-competitive?

A. Because it would allow companies to do other things with their money. There's a dead weight loss to the economy for losing -- from engaging in productive -- unproductive activity.

Q. Meaning lawyers?

A. Meaning litigation costs.

Q. All right. How about the public, is there a public cost of patent litigation?

A. Well, certainly that is one of the -- the costs are -- the costs are ultimately borne by consumers. If patent litigation is allowed and forced to continue, not only lawyers, you mentioned lawyers, but experts as well, and an important cost is -- especially affects companies like Upsher-Smith where the time that is eaten up by litigation, the cost of having senior executives, marketing people and financial people tied up in fighting litigation means that they are not going out and doing their job, which is the job that they should be most productive at, and that is developing pharmaceuticals.

To the extent -- for example, Mr. Troup was the person from Upsher-Smith who was most responsible for the litigation in the spring of 1997. His -- his other primary responsibility was getting Niacor out into the market and negotiating, attempting to negotiate license agreements with others for Niacor. He couldn't be doing that if he was involved in litigation. All of these things eventually add up to costs that consumers pay for.

Q. Sir, have you studied the effects of the patent infringement lawsuits over time, in other words, on public resources, whether the number of these cases is growing or falling?

A. Oh, yes, yes. Part of the database that we maintain and the courses that I teach in patent law and patent damages and the economics of that have traced the -- what's happened to patent law in the last 20 years, and in particular there's been a huge -- a significant increase over time in the number of patent cases filed, now more than 2000 cases are filed a year, and equally important, there's been a -- there's been an increase in the number of patent cases resolving each year, but that number has grown much more slowly than the number of patent cases filed.

So, there's -- over the past decade, there's

been a significant increase in the backlog of patent cases that are in district courts around the country. All of this means that there's a -- that there's a real burden on the court system to the extent that patent litigation continues and continues to grow that has to be paid for.

It -- I didn't mean to imply that it was not a productive expenditure to resolve these cases, but, in fact, it is a cost, and that cost has to be borne, and from the perspective of the court system, it has to be borne by the taxpayer.

Q. I want to ask you a couple of questions, really economic policy questions.

If a rule were created that made it such that multidimensional settlements had to have objective due diligence demonstrated, what do you think the effect would be on multidimensional settlement agreements going forward?

A. They would certainly be a lot more difficult, and being more difficult, it's very likely that fewer of them would be done.

Q. Would that be a pro or anti-competitive result in your view?

A. It would certainly be an anti-competitive effect, because it would probably reduce the number of

pro-competitive as well as anti-competitive agreements.

Q. What's pro-competitive in general about licensing intellectual property?

A. Well, it -- licensing intellectual property is very important to the economy, particularly in industries such as pharmaceuticals. One thing, and I'll stick to the pharmaceuticals example, the company that happens to develop a product or acquire a product as part of an acquisition of another company isn't necessarily the company that's best suited to market that product and bring it to market, and only if a product is taken through the regulatory process, shown to be effective and brought to market can the consumer ever benefit from the pharmaceutical.

An example of that in this case would be for -- would be the ability of Upsher-Smith to market Niacor outside the United States. Upsher-Smith wouldn't have ever been able to do that because of its focus in the United States. It needed to license that if that product was ever going to be exploited outside the United States.

Q. Sir, you've worked on mergers, joint ventures and a variety of intellectual property licensing agreements. Is that correct?

A. I have, yes.

Q. In your experience, do these transactions sometimes come together very quickly?

A. Yes, literally overnight.

Q. Can a transaction of -- a billion dollar merger transaction that's done overnight be a good decision, a good business decision?

A. Certainly. It can be a bad one, too, but...

Q. Does that necessarily vary with the level of due diligence that's performed?

A. Not necessarily.

Q. All right. I want to direct your attention now, sir, to tab 35, and I'd like to show you the Bresnahan test and briefly get your feedback on the Bresnahan test that Dr. Bresnahan proposed in his report and testified about in this Court.

Directing your attention -- are you there? -- to prong one of the Bresnahan test, "Does the patent holder have monopoly power?" What's your opinion of Dr. Bresnahan's implementation or approach to this first prong?

A. The first prong of Dr. Bresnahan's test is not necessarily objectionable in and of itself; however, the way that Dr. Bresnahan defines monopoly power seems to be to look at a branded product and define it entirely in terms of the price that's charged for it.

His conclusion is that if the price falls, there must have been monopoly power.

We've seen that he limits his market to a single brand, and it's very difficult to sustain a monopoly in a single brand. And therefore, the way that Professor Bresnahan defines monopoly power, there's almost always going to be monopoly power. A brand always has monopoly power if you define monopoly power as being the basis for your branding -- for your monopoly power.

Q. How about the third prong?

A. So, therefore, based on the way he does it, he's always going to find the first prong satisfied in a case of a branded pharmaceutical product.

Q. All right. How about the third prong, sir, what is your view of his test, "Is there a payment to the potential entrant to delay its entry"?

A. That is completely dependent on the analysis that's done of the payment. If you're going to determine whether a settlement agreement with a payment is anti-competitive based on the payment, it requires doing an evaluation of the payment and determining whether there's net consideration flowing from one party to the other.

Q. Sir, did Dr. Bresnahan actually perform an

economic valuation that came up with a net present value of the six licenses as of June 1997?

A. He did not.

Q. Now, he talked about a revealed preference test. Do you recall that part of his report?

A. Yes, I do.

Q. All right. Is there any preference revealed by the fact that Upsher-Smith chose to hold on to the NAFTA Niacor-SR rights? Does that reveal a preference?

A. Yes, it does.

Q. What does it reveal?

A. It reveals that Upsher-Smith thought that there was significant value in the Niacor product in June of 1997.

Q. Sir, your report mentions the rule of reason, and I'm not going to ask you about the legality of the rule of reason, but do you find the rule of reason to be informative as a policy guide in this area of "reverse payments"?

A. Yes, I would think it would be essential.

Q. Let me direct your attention now to tab 36. Do you recall those slides being used with Dr. Bresnahan, the three circles?

A. Yes, I do.

Q. Very briefly I'd like your comments on the

three circles and critique, if any, of Dr. Bresnahan's stylized example here.

A. As I understand Dr. Bresnahan's analysis that was represented in this demonstrative, his testimony was that economic theory roundly condemns any agreement such as the one we're dealing with here, and this is an illustration of it. I don't want to comment on whether this illustration comports precisely with economic theory, but it certainly does not comport with the settlement that is involved in this case, the agreement that's involved in this case.

Q. And sir, where is the element of time or patents brought into these slides -- into these pies?

A. It's not clear that it is.

Q. Is that -- what do you think of that?

A. No, I think it has to be, and I think that that -- that perhaps because the element of time is not in here, Dr. Bresnahan misrepresents the implications of the settlement agreement in this case.

Q. Now, you testified at the very top of the morning that there were approximately 60 months that were taken off the life of the '743 patent, and that was just a matter of chronology. Do you recall that?

A. That's right.

Q. Now, sir, does Dr. Bresnahan in prong three of

his test explicitly weigh that as a pro-competitive benefit to the public? Is there any express weighing --

A. No, I don't believe he does that at all. I don't see that in his analysis, no.

Q. All right. Sir, in terms of the settlement agreement, I want to talk about consumers for a second.

Now, would consumers be better off gambling on the litigation result in your view or taking the certainty of the settlement?

A. In general, I think the consumer would be better off taking the certainty of the settlement. Gambling, as you refer to it, involves comparing the likely outcome of the litigation that would have occurred if Schering-Plough had won with the outcome of litigation if Upsher-Smith had won, and in the end, it will involve calculating an average, as I did earlier today, and the average outcome which you're gambling on clearly shows that the consumer would be better off not gambling, not betting on the outcome of the litigation, but taking the settlement for the reasons that I've mentioned before.

Q. Let me show you tab 42, Klor Con M20 Launch, USX 371. Have you reviewed that document?

Oh, I'm sorry, Your Honor, this one's in

camera. My apologies. I thought we were done with in camera.

JUDGE CHAPPELL: Okay, I am going to have to ask the public again to leave the courtroom as we're going into in camera session.

(The in camera testimony continued in Volume 26, Part 2, Pages 6469 through 6470, then resumed as follows.)

BY MR. GIDLEY:

Q. Dr. Kerr, Dr. Bresnahan had a section of his report that talked about economic incentives. Do you recall that?

A. Yes, I do.

Q. And basically he believes or he postulates that a Schering monopoly would give Schering the incentive to share monopoly profits or rents with Upsher-Smith to delay its entry. Do you recall that hypothesis?

A. Yes, I do.

Q. All right, sir. First, do you think that the existence of that economic incentive, even if we assume that it exists, do you think that the mere existence of that economic incentive would lead necessarily to behavior?

A. No, clearly not.

Q. Do you believe that Upsher-Smith had other

economic incentives in June of 1997 in the other direction?

A. Certainly.

Q. What were some of those?

A. Well, one incentive is, of course, to obey the law. Other incentives, though, are the things that I've been describing all morning about their business and the benefits of running their business, the -- making sure that they're able to get the proper return on their intellectual property, being able to enter the market in an effective way to be a competitor in the Klor Con -- with its Klor Con M and -- M10 and M20 products, and just generally to run their business effectively, to get their litigation out of the way and to move forward.

Q. Sir, one of the allegations that was alleged at one point in this case was that the 180 days of the Hatch-Waxman Act had been manipulated. Are you familiar with the 180-day period of the Hatch-Waxman Act generally?

A. Yes, I am.

Q. Are you aware sitting here today of any evidence that Upsher-Smith and Schering-Plough manipulated the start date intentionally in June of 1997?

A. No.

Q. Sir, you've reviewed a lot of documents in this case?

A. I have, yes.

Q. You've reviewed a lot of testimony?

A. Yes, I have.

Q. Have you seen any testimony that would lead you to conclude that there was a conspiracy on the part of Upsher-Smith to further Schering's "monopoly" in K-Dur 20?

A. No.

MR. GIDLEY: No further questions.

JUDGE CHAPPELL: Does Schering have any direct for this witness?

MR. NIELDS: No, Your Honor.

JUDGE CHAPPELL: Okay, then per our agreement, then, the cross of this witness will be conducted after the testimony of Dr. Banakar.

MS. BOKAT: Yes, Your Honor.

JUDGE CHAPPELL: With that, sir, you're excused at this time. Thank you.

THE WITNESS: Thank you.

JUDGE CHAPPELL: We know the microphone works.

And we'll take our lunch recess until 3:00. Thank you.

(Whereupon, at 2:00 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(3:13 p.m.)

JUDGE CHAPPELL: So, complaint counsel is calling a rebuttal witness out of order. Is that correct?

MR. NOLAN: Yes, Your Honor.

JUDGE CHAPPELL: You may proceed.

MR. NOLAN: Thank you, Your Honor. At this time, Your Honor, I call Dr. Umesh Banakar.

JUDGE CHAPPELL: Raise your right hand, please.

Whereupon--

UMESH BANAKAR

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Thank you, have a seat.

THE WITNESS: Thank you.

JUDGE CHAPPELL: State your full name, please, for the record.

THE WITNESS: Good afternoon. My first name is U M E S H, Umesh, last name is Banakar, B A N A K A R.

DIRECT EXAMINATION

BY MR. NOLAN:

Q. Dr. Banakar, what is your occupation?

A. I am a full-time consultant, provide service to pharmaceutical industry and academia worldwide.

Q. How long have you been a consultant?

A. I have been a consultant for over 12 years now, 12-13 years.

Q. And from where do your clients come?

A. My clients are worldwide, including U.S., Far East.

Q. Would you describe your consultancy? In what subject matter is it that you consult, Dr. Banakar?

A. The clientele that I have is from both pharmaceutical industry, both brand name companies as well as generic companies. The activities primarily involve leading the research group -- formulation research group in designing products, evaluating them, both in vitro and clinical, and in that process they create documentation for submission to various regulatory agencies.

Q. In general terms, what type of work do you do for them?

A. I advise them on designing products. I go with the concerned individuals in the labs. I work with them literally, so to speak, get my hands dirty and do the -- do the actual experimentation.

Q. Have you done any work related to NDAs?

A. Yes, I have done work related to NDAs and ANDAs, yes.

Q. What type of work have you done in relation to NDAs or ANDAs?

A. My primary contribution to these activities have been in formulation design, product evaluation, clinical and technology basically.

Q. When you say "product design" and "technology," can you be more specific in terms of what type of product design are you looking at?

A. The product design includes formulation development of immediate release products as well as modified release products, which means sustained release, controlled release products, both for humans as well as for animals, veterinary products.

Q. And have you done any teaching as a professor?

A. Yes, I have done a lot of teaching. I continue to do so worldwide. I have been in academics since 1981, 1980-'81, so it is over 20 years. I've gone through the rungs of -- academic rungs, I guess, including lecturer, professor, associate professor, full professor, as well as Fulbright Scholar.

Q. Where have you taught, Dr. Banakar?

A. I have taught at -- my first job was in India during 1980 where I was a lecturer, then all throughout U.S., I was in academics, Duquesne University, during grad school I taught, then Creighton University, St.

Louis College of Pharmacy, and the most recent was at Butler University.

Q. For how long did you teach at Creighton University?

A. At Creighton University, I was there for six years.

Q. And what specific types of courses did you teach there?

A. I taught pharmaceutics, which is essentially science and technology behind understanding the properties of a drug substance and putting it into an appropriate formulation for human consumption. I taught evaluation of products in human subjects, which is biopharmaceutics or biological evaluation of dosage forms. Then I also taught formulation and development courses where -- how to design products and various other courses.

Q. After Creighton University, where did you teach, Dr. Banakar?

A. I was recruited at St. Louis College of Pharmacy as director of research, as professor of pharmaceutics, as well as section head of their pharmaceutical sciences division, and I was there for almost seven years.

Q. Did you have any management responsibilities

there?

A. Yes, as part of the director of research for the college, I was -- the college being a self-standing entity where it is like a small university, I was responsible for faculty development, including scholarly activity of the faculty, which involved 52 faculty members, four to five departments, and I was responsible for that.

Q. And at Butler College, what did you do there, Dr. Banakar?

A. There I was recruited as chairman of pharmaceutical sciences division, again professor of pharmaceutics, of course, and I was also director of graduate program.

Q. Have you done any teaching related to drug release and dissolution characteristics?

A. Yes, I have done teaching related to drug release and dissolution characteristics, both at the university level as well as worldwide through intensive teaching programs.

Q. As an academic, have you published any papers related to drug release, sustained release?

A. Yes, I have a fair amount of those.

Q. And what other areas have you published in?

A. I have published in evaluation of products,

design of dosage forms. I have published in pharmacokinetics or biological evaluation of products, clinical, numerous areas related to formulation.

Q. Have you done any hands-on research, Dr. Banakar?

A. Yes, I have done extensive hands-on research, and I continue to do so in -- primarily in formulation, development and evaluation.

Q. Would you give us some -- in general terms some examples of the type of research that you would do in a lab?

A. In a lab, we go through the designing of a product with an end objective in mind. That could be a topical formulation, an oral solid dosage form, which is capsules, tablets, sustained release formulations, evaluating polymer films for various purposes, using polymers for various purposes, all sorts of...

Q. Just so that we're clear, when you say "sustained release products," can you tell us in English essentially what type of problem or issue you're addressing when you're designing a sustained release product?

A. The primary problem or the objective that we pursue in case of designing a sustained release product is I have a drug substance which is to be put into a

formulation which releases the drug over a long period of time as opposed to releasing the drug all at once. In the formulation work or as well as the regulatory context, we call it as immediate release if the dosage form releases all of the drug, and if the same drug is put into a formulation which releases slowly over 12 hours, 24 hours, that's a modified release or sustained release product.

Q. And you used the word "polymers." I take it polymers come into your work.

A. Polymers are the ones that are very commonly and frequently used in these formulations, because given the properties of the polymer, we can maneuver and modify the drug dissolution rate or the release rate, thereby we can pick and choose the right combination of polymers, the right polymer for a given drug to meet the objective.

Q. What is the most advanced degree you hold, Dr. Banakar?

A. I have a terminal degree in -- which is Ph.D.

Q. In what subject?

A. My Ph.D. is in pharmaceutics, majoring in pharmaceutics, formulation design and a minor in pharmaceutical chemistry.

Q. And when did you receive it, Dr. Banakar?

A. 1985.

Q. And from what institution?

A. From Duquesne University, Pittsburgh.

MR. NOLAN: Your Honor, may I approach the witness with his vitae?

JUDGE CHAPPELL: Yes, you may.

MR. NOLAN: Thank you, Your Honor.

BY MR. NOLAN:

Q. Dr. Banakar -- by the way, your Ph.D. thesis, in what subject was that?

A. The title of my Ph.D. thesis was Polyethylene as Potential Prolonged Release -- Evaluation of Polyethylene as a Potential Prolonged Release Tablet Excipients, polyethylene being the polymer and tablet being the oral solid dosage form.

Q. What -- have you received any awards in particular, any international awards?

A. Yes, I have -- I received numerous awards in terms of scholarly activities. The ones that I cherish the most are the ones that are given by United Nations, which is the Service to Country Award, and then I have got the Distinguished Service Award for contribution to clinical sciences in India, and I've also received the Fulbright Lecturing Award, which is particularly for the lecturing and not for a lecturing project, meaning

the nature of the way I teach, that contribution as opposed to a course that I teach. So, that is considered to be a very significant one.

Q. Have you done any work with the NIH or National Institutes of Health?

A. Yes. I worked with NIH. I worked with CDC, where I have chaired various study sections looking at various submissions for -- grant submissions, grant applications, and I have been chairperson for these study sections for evaluating these.

Q. Since you received your Ph.D., did you receive any certifications from any programs anywhere?

A. Yes, I did take an intensive one-week course on controlled release technology at MIT, which is certification course.

Q. So, all told, how many years of experience do you have in the field of pharmaceutics?

A. Over 20 years.

Q. And approximately how much of that time has been in the area of pharmaceutical coatings?

A. At least more than 15-16 years.

Q. And have you served as an expert in patent litigations?

A. Yes, I have.

Q. And can you tell us in general terms without

offending any confidentiality requirements what types of matters those have been?

A. The patent litigations that I have been involved with were essentially as expert witness in interpreting the patent claims as they relate to the construction of the product, formulation, and then giving expert reports in terms of interpreting the formulations.

Q. And by the way, just a couple of areas I haven't asked you, do you belong to any professional associations?

A. Yes, I do.

Q. Which ones, if you could name some briefly?

A. Some of the ones will include Controlled Release Society, then American Association of Pharmaceutical Scientists, India Pharmaceutical Association and numerous others.

Q. Are you an editor or referee of any pharmaceutical journals?

A. Yes, I was the founding editor of a new journal, then I am also on the Editorial Advisory Board of a few international peer-reviewed scientific journals.

MR. NOLAN: Your Honor, at this point I would like to offer Dr. Banakar as an expert in

pharmaceutical coating and the design and evaluation of pharmaceutical dosage forms, both intermediate and sustained release.

MR. LAVELLE: No objection, Your Honor.

MR. CURRAN: No objection, Your Honor.

JUDGE CHAPPELL: The motion is granted.

MR. NOLAN: Your Honor, before we go on, I believe that throughout the examination there may be references to information which could touch on confidential material, so at this point I think it would be wise to clear the courtroom of people who -- you know, not associated with the parties.

JUDGE CHAPPELL: You're intending to have his entire direct exam in camera?

MR. NOLAN: My understanding -- I'm trying to be sensitive to the interests of Upsher-Smith -- is that in some areas it's very difficult, Your Honor, to talk about the particular issues without at least indicating that -- what the formulation may be. If I'm wrong about this, I'd ask that they correct me.

MR. CURRAN: Well, Your Honor, we certainly want to preserve the trade secret and proprietary information relating to Upsher-Smith's formulation. I don't know what that means in terms of whether the entire direct exam has to be in camera or not.

JUDGE CHAPPELL: And I have a responsibility to maintain a public record whenever and when possible; however, I also have a responsibility to maintain confidentiality of parties' documents and especially those of nonparties who are not present here.

MR. LAVELLE: Your Honor?

JUDGE CHAPPELL: Has the witness been instructed -- Dr. Banakar been instructed -- does he know what areas are in camera, what subjects, what issues, what documents?

MR. NOLAN: I think -- not -- just in general terms. He's aware of the formulation characteristics and the like, and I suppose he would -- we have not given him specific instructions, because we don't intend to use particular documents other than the patent, but as he comments about the patent, I am concerned that there could be aspects that touch on the polymers or what have you, their use, and it's conceivable that there could be a problem.

JUDGE CHAPPELL: Mr. Lavelle?

MR. LAVELLE: I was just going to suggest if it's helpful, Your Honor, we have not cleared the courtroom in the past when talking about the ESI product, although we have had concerns and tried to be careful on the Upsher product. So, certainly perhaps

one part that we could stay on the public record would be whatever he's going to discuss about the ESI issues.

MR. NOLAN: Right.

JUDGE CHAPPELL: Are you saying that we have been remiss in allowing information or are you saying --

MR. LAVELLE: No, I don't believe so. I don't believe it's confidential, Your Honor.

JUDGE CHAPPELL: So, the ESI information was not granted in camera status?

MR. LAVELLE: That's how we handled our witnesses, that's right.

MR. NOLAN: Well, if it helps in terms of the organization here, we first intend to talk about just what he -- Dr. Banakar has looked at and then fairly quickly move into the substance of the Upsher-Smith area and then finish with the ESI.

JUDGE CHAPPELL: Okay, so you're at a point now where you have nothing to question the witness on that is not going to touch on in camera information?

MR. NOLAN: Perhaps five minutes worth and then -- I was just trying to be on the safe side, but we could go for another five minutes.

JUDGE CHAPPELL: Well, to be on the safe side, we are not going to leak in camera information, but

also to be on the safe side, I have an obligation to the public, so let's keep that in mind. So, let's proceed until we get to the point where we need to clear the courtroom.

MR. NOLAN: Yes, Your Honor.

JUDGE CHAPPELL: Thank you.

BY MR. NOLAN:

Q. Dr. Banakar, did you prepare an expert report in this litigation?

A. Yes, I did.

Q. And what type of materials did you review in doing this work?

A. In doing this work, I reviewed the '743 patent, the prosecution history, the development report of Upsher-Smith, the various expert reports that were submitted during the patent litigation in 1996-'97, the rebuttal reports, then the experimentation that Dr. Banker as well as Dr. Langer relied on, that come to mind.

Q. About how many hours did you spend doing the work leading up to today?

A. It was more than 100 hours for sure.

Q. And at what rate are you reimbursed for your work?

A. I am reimbursed at a rate of $480 per hour.

Q. With respect to the '743 patent, will you tell us what the invention is in the '743 patent?

(Brief pause.)

JUDGE CHAPPELL: You may proceed.

Give me one second, please.

(Pause in the proceedings.)

JUDGE CHAPPELL: Go ahead, thank you.

MR. NOLAN: Yes, Your Honor.

BY MR. NOLAN:

Q. Dr. Banakar, would you tell us generally what the invention is in the '743 patent?

A. The way I understand it when I went through the patent, this patent is all about a -- designing a sustained release product, particularly oriented for potassium chloride, and it is an oral solid dosage form, which is a tablet. The product has potassium chloride, which is in particulate form, which is coated with a polymer, which has a combination of two polymers actually. Ethylcellulose is the base one, which is combined either with HPC or PEG, and then -- PEG is polyethylene glycol, HPC is hydroxypropylcellulose -- and then these coated particles, along with other excipients, which are standard tableting excipients, these are compressed into a tablet formulation. The dissolution or drug release properties of that tablet

formulation are evaluated in that patent, and that is the invention.

Q. Are there any particular portions of the '743 patent that you think are pertinent to identifying what the essence of the invention is?

A. The essence of the invention is that the particles of potassium chloride are coated with a combination of two polymers, ethylcellulose and HPC, which are referred to in terms of a proper balance, and that proper balance is in terms of a ratio between these two polymers that are by weight added to that composition, and the coating material that results from this composition is -- is expressed as a combination of these two in certain percentages. That you will find in column 4 of that patent.

Q. Nicole, could we bring up column 4, please, bring up between lines 8 and 9 and work our way down.

JUDGE CHAPPELL: I think the people that control the heat are getting even with me. It's 79 degrees up here, so -- go ahead, Mr. Nolan.

MR. NOLAN: Yes, thank you, Your Honor.

BY MR. NOLAN:

Q. Dr. Banakar, feel free to draw your attention to particular aspects of the patent here.

A. Yeah, the -- this -- these two lines clearly

indicate the weight ratio of ethylcellulose and HPC. Then if you follow down, in the next paragraph where it says -- okay, line 22, it says by providing the proper balance of ethylcellulose, an HPC polymer film can be formed. So, that indicates that balance is that weight ratio which we are looking at, and then further down in lines 32 onwards, it says that the polymeric coating is clearly a combination of ethylcellulose and HPC on the crystals, make up whatever the percentage combination that we are looking at. So, there is clear indication of what is involved here.

Q. Dr. Banakar, you have referred to the proper balance as used in the patent. What is the significance in your mind of the proper balance? What does that mean in terms of the way the patent works, the invention works?

A. As a formulation scientist, whenever a formulation person is designing a product and comes across components in a composition which have to be in a certain -- a certain combination and certain percentage amounts in order to maneuver that combination to an objective, and usually that objective is the amount of drug released over a period of time. So, the proper balance in a formulation scientist's perspective is the amount of one -- if there are two

ingredients, then amount of one and two put together. That's the proper balance, which is usually expressed in terms of weight ratio.

Q. Does the proper balance have anything to do with the permeability of the formulation?

A. Yes, the proper balance will ultimately lead to the permeability, thereby the drug release properties that we are looking at, which will give us that.

MR. LAVELLE: Your Honor, I move to strike the last as outside the scope of his expert report. There's nothing in his report about this notion of proper balance at all, and although I don't have any problem with some latitude, clearly when he starts attaching that to release rates and the like, he's outside the scope of his report. I ask that it be stricken.

MR. NOLAN: Your Honor, when Dr. Banakar was deposed, I believe that counsel asked him questions concerning the patent and the proper balance and the like and that Dr. Banakar at that time touched upon this aspect of how the patent works. So, I don't think there is anything new here.

JUDGE CHAPPELL: Mr. Lavelle, I'll make you the same offer I made to Mr. Eisenstat this morning. After you've conducted your cross, if you demonstrate that

we're hearing opinions you didn't know of before, I'll reconsider your objection.

MR. LAVELLE: Very good. Thank you, Your Honor.

JUDGE CHAPPELL: You may proceed.

MR. NOLAN: Thank you, Your Honor.

BY MR. NOLAN:

Q. Dr. Banakar, with respect to the Upsher case, have you reviewed any specific materials for that -- for that work?

A. I've reviewed a lot of material relating to Upsher's case. I have reviewed the development report. I have reviewed the various expert reports as well as the deposition of Ms. Vickie O'Neill, the rebuttal reports, the experimentation that was done.

Q. Can you name just very briefly the names of some of the expert reports you've reviewed, just so that we know?

A. Dr. Banker, Dr. Langer, Dr. Block, Dr. Robinson. This was mostly in relation to -- from formulation perspective in relation to Upsher's case.

Q. Did you read any depositions or trial testimony of these individuals?

A. Yes, I have read it as well.

MR. NOLAN: Your Honor, before we go further, I

think at this point we will be getting into some sensitive areas, so I would ask that the courtroom be cleared.

JUDGE CHAPPELL: Okay, at this time we are going into in camera session. I will have to ask the public to leave the courtroom.

(The in camera testimony continued in Volume 26, Part 2, Pages 6471 through 6487, then resumed as follows.)

JUDGE CHAPPELL: Mr. Nolan, please stand by until the public has entered.

MR. NOLAN: Yes, Your Honor.

JUDGE CHAPPELL: You may proceed.

MR. NOLAN: Thank you, Your Honor.

BY MR. NOLAN:

Q. Dr. Banakar, have you reviewed any materials as part of the ESI-Schering litigation?

A. Yes, I have.

Q. And what specific expert reports or other materials have you reviewed?

A. I have reviewed Dean Banker's comments on -- expert comments on ESI's product. I have reviewed the experimentation done by Bob Langer -- what experiments he relied on really. He did not do any experiments himself. I also looked at Dr. Peppas' experiments on

dissolution. Then I also looked at Hopfenberg's experimentation, Bob Langer's or Dr. Langer's experimentation, SEMs, FTIRs, DSCs, all of these.

Q. Did you analyze the technical issues in the Key versus ESI case?

A. Yes, I have.

Q. And what were the main issues in that case?

A. The main issue really is the '743 states that a coating material which we already looked at in column 4 is a combination of ethylcellulose and HPC. All the examples which -- which are provided in the patent also all clearly indicate that there is a combination or a mixture of these two polymers, which are solubilized, and then that solution is applied, whereas ESI's product, the way it is constructed is they first coat the particles of potassium chloride with ethylcellulose, and physically then they coat the next one, which is HPC. So, there is a distinct difference in the way it is manufactured. As a matter of fact, there is one extra step in the case of ESI product.

Q. Nicole, for just a minute, could we bring up column 8 and line 18 in the patent, 18 through about 28 or 30, I'm sorry.

Where it refers to a "coating material," would you care to elaborate, Dr. Banakar, as far as how do

you understand the term "a coating material" as expressed in claim 1 of the '743 patent?

A. As expressed in claim 1, a "coating material" here indicates that there is a combination of two polymers or two components, where it clearly states the coating material comprising -- or the next line actually, which is highlighted after that, the coating material comprising ethylcellulose in the amount in the range of about 9 percent to about 15 percent by weight based on the total weight of and at least one -- "and," it is not "or," it says "and," so it is a combination.

Q. And Nicole, if we could turn to column 5 between line 25 and 32, bring that up.

A. Column 5 or 6?

Q. Column 5, the manufacturing process.

Let me just ask you, in formulating your analysis, did you look at this provision at all, Dr. Banakar?

A. Yes, it talks about the entire business of this invention is to look at the dissolution properties or the drug release ability.

Q. And just one more before we go on, Nicole, if we could go to column 3 between lines 8 through 12.

Do you --

A. It says, again, the same thing as -- it is

specifically oriented towards -- it specifically mentions, it is specifically for a controlled release potassium chloride tablet.

Q. When we are referring to a coating material that's a mixture, can you just elaborate in general terms what -- is this a single thing?

A. A mixture in physical chemistry, which is standard science, fundamental science, a mixture is when I have two or more components intimately mixed together which are uniform, uniformly dispersed, and it could be in one phase or two phases.

For example, if I have two liquids mixing together, then it will be a uni-phase system. If I have two solids mixing together, it is a solid mixture. But in this case, we have two polymers which are going to be solubilized before they are applied, so it will give me a mixture which is giving me a unique -- a uni-phase or single-phase solution in which both the components or both the polymers are mixed uniformly.

Q. How do you understand ESI's product to be designed, Dr. Banakar?

A. ESI's product, the way I understand it, is -- we have a potassium chloride crystal. On that crystal, there is coating which is of ethylcellulose, and then that coated particle is then coated with the layer of

HPC. So, it has two distinct coats or two steps which are separate, independent of each other, mutually exclusive, with such a product.

Q. And with respect to the second coat, for what purpose is that used in the ESI product?

A. Again, to refresh ourselves, number one, we have to keep in mind that we are looking at small particles of potassium chloride which are coated with ethylcellulose. Ethylcellulose is impermeable. So, now if I coat it with a water-soluble polymer, and now this composition or seeds, which have two coats, are put together and compressed into a tablet, that tablet will disintegrate, the polymer will dissolve, which is HPC, the polymer will dissolve and will create the permeability requirements for the drug to come out of those small coated seeds with ethylcellulose.

Q. And for what purpose was the HPC used in the ESI product?

A. The way I think and I look at it is HPC was used to -- in this case as a separate coating and creating a facility where when the tablet disintegrates, the polymer outside of it will dissolve, thereby it will create the right conditions for the drug to come out from an impermeable polymer.

Q. Did you reach any opinion on whether the ESI

product literally is the same as that invention claimed by the '743 patent?

A. I'm not a lawyer, but literally the way I understand it is yes, the '743 has potassium chloride, ethylcellulose and HPC. All these three components are in the ESI product also. So, the -- literally, they are -- component-wise, there are all the ingredients that are in '743 which are also -- which we see in ESI's product.

Q. But are -- those ingredients, are they in the same formation or different?

A. The way we look at it, we term it in formulation science, is structurally ESI's product is different compared to '743 or the embodiment of '743, which is K-Dur, and that's what makes it different.

Q. When you say structurally it's different, are you saying it works in the same or a different way?

A. It will work in different way. The product is built up or structured differently. As I said, that these two coatings are mutually exclusive. These two polymers that are used are not in a mixture. So, that's where the differences lie.

Q. Well, in a literal sense, does the '743 patent -- I mean, does the ESI product have a coating material in the way that the'743 patent calls for one?

A. No. The coating material as per '743 and the plain language of '743 and the understanding of it is it has to be in the mixture form, uniformly mixed and applied as a single uniform coat, whereas ESI product has two different coating steps.

Q. So, if I understand you correctly, you're saying that while it uses the same ingredients, it literally does not have a coating material as ESI's product does -- as the '743 patent does.

A. That is correct.

MR. LAVELLE: Objection, leading.

THE WITNESS: That is correct.

MR. NOLAN: You should wait until the Judge has ruled.

THE WITNESS: Sorry.

JUDGE CHAPPELL: That was a leading question, but the cat's out of the bag. I think you'll have to speak up sooner. I don't think he sees you standing up.

MR. LAVELLE: Okay. Thank you, Your Honor.

BY MR. NOLAN:

Q. Are you aware, Dr. Banakar, of arguments by Schering that the ESI product is a mixture of EC and HPC?

A. I didn't follow the question. May I hear it

again, please?

(The record was read as follows:)

"QUESTION: Are you aware, Dr. Banakar, of arguments by Schering that the ESI product is a mixture of EC and HPC?"

THE WITNESS: Yes, that is their contention. That's what their argument is.

BY MR. NOLAN:

Q. And have you reviewed the expert report of Dr. Langer?

A. Yes, I have reviewed the expert report of Dr. Langer.

Q. And have you reviewed his testimony as well in this matter?

A. Yes, I have reviewed his testimony.

Q. To what extent do you understand him to be claiming that the ESI product is a mixture?

A. He has -- he has provided or relied on three pieces of information. One is he has looked at the SEMs, which are scanning electron micrographs of the coated beads, the -- he has also relied on the dissolution experiment --

MR. LAVELLE: Your Honor, I have to object to this as outside the scope. A, there's nothing in his expert report on this, and when I asked this witness at

his deposition what in your expert report is rebutting Dr. Langer, he said nothing. So, this is clearly outside the scope of his expert report and the nature of his testimony in deposition. He told me in his deposition he was not rebutting anything Dr. Langer said.

MR. NOLAN: Your Honor, in his deposition, he -- Dr. Banakar was questioned at some length about the SEMs as well as the other materials that were part of Dr. Langer's study, and in fact, there were numerous questions and answers related to those -- to those SEM slides, including what Dr. Banakar saw in those slides. So, I think it's fair notice to the other side that Dr. Banakar does have views here, and I would not go further than the general area that Dr. Banakar covered in his deposition.

JUDGE CHAPPELL: Do you disagree that he said at his deposition he was not rebutting Dr. Langer?

MR. NOLAN: I -- I don't --

MR. LAVELLE: I'll read it, Your Honor, if you like.

JUDGE CHAPPELL: Do you want to take this witness on voir dire, Mr. Lavelle?

MR. LAVELLE: I would, just very briefly.

JUDGE CHAPPELL: You may.

VOIR DIRE EXAMINATION

BY MR. LAVELLE:

Q. Dr. Banakar, there is nothing in your report relating to Dr. Langer's results, correct?

A. I have not seen the report, but --

Q. Well, here.

May I approach?

JUDGE CHAPPELL: Yes.

BY MR. LAVELLE:

Q. It's SPX 750. Please take a look at it, sir. Look through it and tell me which paragraphs rebut anything that Dr. Langer said, sir.

A. I remember you were asking me questions on dissolution and SEMs and all of that, but that's all.

Q. My question is, what in your report rebuts Dr. Langer? Which paragraphs there in your report are directed to Dr. Langer's tests? None of them, correct?

A. Right, but the report is the technical assessment.

MR. LAVELLE: Your Honor, I move to strike everything after "right."

MR. NOLAN: Your Honor --

MR. LAVELLE: Let me finish my voir dire and then I'll tender him back to you.

BY MR. LAVELLE:

Q. Sir, were you asked this question in your deposition:

"QUESTION: What in your expert report, Exhibit 1, rebuts any expert opinions of Dr. Langer?

"ANSWER: Nothing directly as such."

Were you asked that question and did you give that answer?

A. Yes, you are reading that, but --

MR. LAVELLE: Your Honor, I ask that this witness' testimony about Dr. Langer be stricken.

THE WITNESS: It qualifies with "as such." "As such" doesn't mean the whole thing.

MR. NOLAN: Your Honor --

JUDGE CHAPPELL: Hang on just a second. Everybody just calm down.

Are you going to let this witness see his deposition transcript?

MR. LAVELLE: Oh, absolutely. It's in front of him. It is --

JUDGE CHAPPELL: Because he didn't seem convinced, Mr. Lavelle. I'd like you to let him look at it.

MR. LAVELLE: It's in front of him, Your Honor, and I'll give you a cite.

MR. NOLAN: May I approach the witness, Your

Honor, to show him -- to take a look --

JUDGE CHAPPELL: Yes.

MR. LAVELLE: SPX 1280, Your Honor, and it's on page 20.

JUDGE CHAPPELL: And I think, Mr. Lavelle, you had moved to strike something, but I'm going to overrule that since you didn't give me a chance to rule.

MR. LAVELLE: I apologize, Your Honor.

JUDGE CHAPPELL: Your witness. We're still on voir dire here.

BY MR. LAVELLE:

Q. Well, if he has answered my question -- did you give that testimony?

A. I was qualifying the answer. I said, it says, "as such."

Q. Right.

A. That does not mean all of it, whereas I know these are actual pages now where you asked me about Figure 8d, then you asked me about dissolution data, then you asked me about FTIRs. So, yes, there is enough here, questions that you did ask me, to go to that.

Q. Absolutely, but my question is, did you offer any opinions in your expert report that rebut Dr.

Langer's testimony, sir?

A. The opinion itself entirely rebuts it anyway, because it doesn't specifically say that it is this point or that point, but the entire contention says it.

Q. What paragraphs of your report talk about Fourier transform infrared spectroscopy, sir?

A. I did not say it's a specific point in the expert report.

Q. Which paragraphs in your expert report talk about differential scanning calorimetry, sir?

A. Same answer.

Q. None of them, right?

A. I said none of them, yes, but the entire report is really rebutting the whole notion of single layer being formed.

Q. Which paragraphs of your report talk about scanning electron microscopy?

A. Same answer.

Q. None of them, right?

Your Honor, this witness has not provided opinions in any form that are capable of being prepared and cross examined. He was asked questions about some of these subjects at his deposition, but that's a completely different matter from him giving us fair notice of opinions that we can cross examine him on. I

think this shouldn't be permitted, Your Honor.

MR. NOLAN: Your Honor, may I approach the witness and show him a particular paragraph and then do a little voir dire of my own?

JUDGE CHAPPELL: Yes, we're still considering the issue of whether to strike this portion of his testimony.

VOIR DIRE EXAMINATION

BY MR. NOLAN:

Q. Dr. Banakar, if you could look at paragraph 20 of your expert report, what does paragraph 20 refer to?

A. After reviewing the expert report submitted in connection with this proceeding and the prior District Court proceeding, I conclude that there is at least substantial evidence that with respect to ESI's product that the ethylcellulose and HPC were not mixed in any coordinated fashion to form a single coating. That is 21.

Q. Now, in your deposition, were you asked questions by Mr. Lavelle about whether or not the -- there was mixing?

A. Yes.

Q. And were you asked questions about your analysis of the SEMs?

A. Yes.

Q. Were you asked questions about your analysis of the FTIRs?

A. Yes.

Q. And were you asked some questions about dissolution studies?

A. Yes.

Q. And did you give answers to those questions?

A. Yes, to the best I could.

JUDGE CHAPPELL: Okay, the only way this is going to be manageable is it doesn't matter whether it was Dr. Langer or Dr. Anybody Else. The standard is were expert opinions given to the other side to enable them to prepare for trial, and when all is said and done, if they weren't, then they will be disregarded.

So, I'm not sure if I'm sustaining your objection or not, because that -- it doesn't matter to me if he said I'm rebutting Dr. Langer. That's unmanageable from where I sit. It's -- it's the subject matter. It's the issue. It's the test, the surfactant or whatever that matters to me. So, I'm talking about opinions and areas of opinions rather than the names of people.

MR. LAVELLE: All right, and in fairness, Your Honor, he's already said that none of the three areas that Dr. Langer's tests go to he addressed in his

report. The objection is not to the name; the objection is to the fact that the substance of his testimony isn't in his report, and he disavowed that that was what he was going to testify about.

MR. NOLAN: Your Honor, in all fairness, with respect to this particular expert report, it was mentioned specifically in there that he takes issue with the idea that there was mixing. This is -- it's there in his report.

Now, I'll grant you that there are not, you know, ten paragraphs referring to particular paragraphs -- SEMs or particular FTIRs where he has a particular point to make, but the opportunity to ask Dr. Banakar those questions was in his deposition, and Mr. Lavelle took that opportunity, and I think in all fairness, Dr. Banakar should be permitted to provide his rebuttal testimony with respect to the issue of mixing.

JUDGE CHAPPELL: So, you're representing to me that this line of questioning goes to mixing?

MR. NOLAN: Correct.

JUDGE CHAPPELL: And your position is it's not?

MR. LAVELLE: Well, Your Honor, my position is we're entitled to more notice than the fact that he's going to challenge the mixing issue. If he intended to

rely at the trial on challenging Dr. Langer's differential calorimetry or his infrared tests or his SEM photos, we were entitled to know his opinions in advance of his deposition to cross examine him.

It's not sufficient for them to say we contest the infringement issue or we contest the mixing issue. We were entitled to know the substance of his opinions before his deposition, and we got none.

JUDGE CHAPPELL: I never saw the deposition testimony that everybody's referring to, that he was asked about. Did he say he was not rebutting testimony of Dr. -- or the opinion of Dr. Langer?

MR. LAVELLE: Almost in those words. I asked him:

"QUESTION: What in your expert report, Exhibit 1, rebuts any expert opinions of Dr. Langer?

"ANSWER: Nothing directly as such."

On page 20 of the transcript, and I'll get you a copy, Your Honor.

MR. NOLAN: Your Honor, it was always clear that Dr. Langer's reports concerned the mixing issue, and the mixing issue was specifically questioned in the deposition, and I am certain that Dr. Banakar mentioned in his deposition that he disagreed with Dr. Langer's conclusions and he disagreed with the conclusions of

Dr. Peppas on the dissolution, and he provided particular criticisms, and, you know, I think there's been fair notice. Certainly that testimony is available for Mr. Lavelle to cross examine Dr. Banakar on. And it goes on for a number of pages.

I'm not prepared at this particular point to go through ten pages and say here's the ten pages that Dr. Banakar testified about, but I think anyone fairly looking at that transcript will see that Dr. Banakar was questioned at considerable length about the question of mixing and that he gave answers that were direct and forthright, and this Court should hear his views.

JUDGE CHAPPELL: All right, here's my ruling, and you attorneys are going to have to figure it out. Any opinions that you were made aware of during the deposition, he's going to be able to tell me those. That's the bottom line, and we'll take it from there.

With that, the objection is I suppose partially sustained and partially overruled.

MR. LAVELLE: Thank you, Your Honor.

MR. NOLAN: Thank you, Your Honor.

DIRECT EXAMINATION (cont)

BY MR. NOLAN:

Q. Did you analyze the SEM studies of Dr. Langer,

Dr. Banakar?

A. Yes, I have looked at them and I have studied them.

Q. And during your deposition, did you point out any particular SEM that you thought was worth looking at?

A. Yes, I specifically remember I referred to Figure 8d.

JUDGE CHAPPELL: Hang on a second, before -- as I have read the CaseView, I just want to be real clear. My ruling includes, after cross examination, I'll revisit the issue, if necessary. Does everyone understand?

MR. NOLAN: Yes, Your Honor.

MR. LAVELLE: Yes, Your Honor.

JUDGE CHAPPELL: When I say you attorneys are going to have to figure it out, I don't mean you have to figure out my ruling. I mean you have to figure out whether you come back to me after you have done all of the examination. Any questions?

MR. LAVELLE: Thank you, Your Honor, no questions.

MR. NOLAN: No questions from me.

JUDGE CHAPPELL: Thank you, you may proceed. Do you need Susanne to repeat the last question or was

it answered? I think we're ready for the next question.

BY MR. NOLAN:

Q. Okay, if we could bring up -- Nicole, could we bring up Figure 8d in Exhibit 1679?

What about Figure 8d did you point out at your deposition?

A. This is not the best diagram here, because it is all photocopied and what, but 1 is the core and then on top of 1 there are two distinct layers that I could see even from a copied picture.

Q. Um-hum.

A. And that tells me that those two layers are separate. It is not a uniform mixture that is applied.

Q. It may help -- we'll try using a color copy that Mr. Lavelle provided to us at one point, and have you ever been -- have we received the original -- we have never received the originals, correct?

A. No, we never received the originals. As a matter of fact, these were the ones that were given me very close to the time, to us very late in time.

Q. Okay. Does this help in any respect?

A. Yeah, it helps a little bit. We can see that the immediate region after the core, which is way at the bottom, the white region, is the core, and then on

top of it there is the first layer, and then you see a fairly dark region, that's where the second coat comes on. So, it is fairly clear.

Q. And what are you trying to draw to our attention with respect to this particular slide?

A. That one -- both the coatings are not mixed. Number two is the application of two different steps, which is clearly seen here. It is not a uniform mixture of both the polymers that is applied.

Q. And what do you see at the top of 8d?

A. That's -- that's the surface.

Q. Below the surface, what is that first area?

A. That's the one where the second layer -- top-most layer is, and then the bottom layer is the next one.

Q. What would you imagine that layer to be composed of?

A. As per the construction of the product, that would be the layer for HPC.

Q. And did you say that in your deposition, Dr. Banakar?

A. Yes, I did.

Q. Now, did -- during the deposition, were you asked questions about the dissolution studies of Dr. Hopfenberg?

A. Yes, I was.

Q. And did you have an opinion about those studies?

A. Yes, I have significant opinion about those studies as well as the ones that were conducted by Dr. Peppas.

Q. Did you express that opinion at your deposition?

A. Yes, I expressed that very vividly, I remember that.

Q. And in general terms, what did you say about the dissolution studies?

A. Of?

Q. Of -- well, let's start first with Dr. Hopfenberg and then Dr. Peppas.

A. Dr. Hopfenberg had an objective to evaluate the dissolution characteristics of the coated beads, and the specific objective was to look at HPC, which is a water-soluble polymer. Given the structure of ESI, it stands to reason that when I placed that particle, which is coated with EC first, ethylcellulose, which is insoluble, and then with HPC, I would see HPC dissolving out very rapidly, and that's what the results show, and that clearly indicates that, yes, there are two distinct layers which come out

separately.

There was also questioning regarding water treatment, methanol treatment and water treatment, and I also said there at that point I was shown a table where there was some EC also coming out, and I did indicate that, well, when I placed that particle -- coated particle and look at it for a long time, there will be gradient set-up where we will see both the polymers coming out. So, that does not mean anything, whereas the first few minutes, almost first minute, is very critical, because HPC is a highly soluble outermost coat. It should show up in the medium -- water medium just as rapidly as it can be, and that's what we see in case of Hopfenberg experiment.

Q. And you find that -- you said at your deposition that was consistent with what?

A. That was consistent with what I feel is correct, and that was also consistent with how well the construction of the product is. Dr. Langer tried to come from the other end, saying that, well, that test is not a USP test, and I took a major objection to that, because the fundamental of a USP test is completely different, which is lost in Dr. Peppas' experimentation. I can explain it if you want me to.

Q. Now, just as background related to the

explanation, in the area of dissolution, what type of -- how extensive is your knowledge in that area?

A. I have significant, far extensive knowledge in dissolution. I am considered an expert in dissolution testing. Very recently, we had one or two patent litigation cases which were focused on dissolution, and my experimentation, the judge was persuaded, and the judge found that evidence was compelling.

Q. What issues did you raise at your deposition with the dissolution approach of Dr. Peppas reviewed by Dr. Langer?

A. Dr. Peppas used a USP dissolution test, which is a compendium of dissolution tests, but there is a fundamental error in that, because that test is, number one, for finished dosage form, not for an intermediate or not for looking at an excipient. That is very clear from the requirement that the USP dissolution tests require the quantification of amount of drug released and not amount of excipient released. So, the object there is to evaluate a finished dosage form, and that's why all the drug release testing that is done.

But here, we are not interested in drug release. We are interested in the excipient release here, and the construction of the product is -- becomes very critical. If I have a very water-soluble

component, right off the bat, coming into contact with water, then that will solubilize rapidly, and that's the experimentation. That dissolution test, USP dissolution test, is the wrong test to use in this situation.

Number two, the quantification of drug release, showing a drug release, has no meaning here, because the drug will release out after there is some kind of a gradient set-up where these polymers and the entire composition starts to work in that medium. We are not interested in the drug release. We are interested only in the excipient release. So, the -- there is a basic -- basic, fundamental error which has occurred there, and relying on that and saying that, see, because there is drug release and because we see all of this that it's a mixture, it is a far-fetched conclusion.

Q. When you use the word "excipient," just so we all understand, what is an excipient?

A. An excipient is a component in a formulation which is inert, which is used for specific purposes, either for structuring the product with the properties that you want, where it is not active, it is not a drug substance, and it is generally regarded as safe to be used in a formulation for human consumption.

Q. So, in sum, based on your deposition testimony to the extent that you sit here recalling it today, what was your conclusion regarding whether Dr. Langer's experiments showed mixing of the HPC and EC?

A. In relation to his reliance on dissolution tests done by Dr. Peppas, I completely disagree, because those results really have no meaning, because the entire test used is the wrong test.

Q. And in relation to the other tests, including SEMs, did you express any opinion?

A. Yes, in the -- with regard to SEMs, some of the opinions that I expressed, I don't recall all of it right -- sitting here right now, but SEMs, FTIRs, there is still a big question as to whether they are conclusive or not. It tells us something in terms of what the construction of the product, but the number of SEMs that were drawn are far too many, and only seven were reported. So, I'm not sure what is -- on what basis those SEMs were selected, but still, it does show difference.

MR. NOLAN: No further questions, Your Honor.

JUDGE CHAPPELL: How much cross do you think you have?

MR. LAVELLE: An hour, Your Honor.

JUDGE CHAPPELL: Okay, why don't we take our

afternoon break, and then, of course, if we get into 7:00 or 8:00 p.m., we will take another one later, but let's break until 4:55.

(A brief recess was taken.)

JUDGE CHAPPELL: Before we get started, Mr. Lavelle, I just wanted to point out to all the parties that we now seem to have come to the expert opinion by deposition expansion, so if anybody wants to rethink what they're offering and how they're approaching this, you're going to need to let me know by the end of the day, because we were operating by the expert opinion given as an expert report rule, and I really haven't been pushed beyond that until this afternoon.

MR. NOLAN: Your Honor, Ms. Bokat may be able to help me out here, but it is my specific recollection that there is a prior instance in this case where at least one witness, the matter came up in his deposition, and you said if it was in his deposition, that's fine.

JUDGE CHAPPELL: I probably didn't have any strong objection to that if I did that. I'm just pointing out, just so everybody knows now, at least from this point forward, the attorneys have managed to expand what expert opinions are going to come in in this case. Whether you've been operating under that

assumption or not, that's where we are now, and with that, you may proceed with your -- first of all, are both respondents going to cross examine this witness?

MR. CURRAN: If I do on behalf of Upsher, Your Honor, it would take no longer than four or five minutes.

JUDGE CHAPPELL: Okay.

Proceed.

MR. LAVELLE: Thank you, Your Honor.

CROSS EXAMINATION

BY MR. LAVELLE:

Q. Dr. Banakar, you weren't an expert witness in the Upsher case, were you?

A. That is correct, I was not.

Q. And you weren't an expert witness in the ESI case, correct?

A. That is correct.

Q. Okay. And you didn't consult with either Upsher or ESI in connection with the original litigation, correct?

A. That is correct.

Q. And you didn't form any of the opinions you testified to here today until October of last year, correct?

A. That is correct.

Q. And you spent only 20 hours in forming your opinions set forth in your expert report, correct?

A. I remember saying 30 or greater, yes.

Q. Well, do you have your deposition transcript in front of you, sir? It's SPX 1280. If you would go to pages 20 and 21, please. Why don't you go to page 18, please.

A. Yeah, probably at least 20 plus, I said that, yes.

Q. "QUESTION: So, you're comfortable saying you spent 20 hours of time on the matter at the time you signed your report?

"ANSWER: Yeah. That would be fair."

A. Yes.

Q. Was that your testimony?

A. That is correct.

Q. Okay. So, you put 20 hours of time roughly into preparing your report, correct?

A. Preparing the report, yes.

Q. Okay, thank you. And your report is SPX 750 in your book, correct?

A. I think you showed me that recently, yes.

Q. Just double-check, please.

A. Yes, that is correct.

Q. And in paragraph 3 of your report, you list the

materials that you reviewed during those 20 hours, correct?

A. Twenty hours was spent in the -- on the report. I spent -- earlier, I might have read a lot of stuff around this.

Q. The materials you read during the 20 hours are the materials you listed in paragraph 3, correct?

A. Not really.

Q. No?

A. No. I mean, I -- I must have spent more hours reading this, but the 20 hours was part of the report generation.

Q. I see. You didn't read the entire record in the Upsher case, did you, sir, before forming your opinions?

A. Where are we on this?

Q. I'm asking you, did you read the entire record in the Upsher case before forming your opinions?

A. The entire record? You will have to help me there.

Q. Okay. You didn't read all of the depositions in the Upsher case, correct?

A. At that time?

Q. Right, before you formed your opinions, sir.

A. Not all of them.

Q. All right.

A. No.

Q. And you didn't read the depositions, all of the depositions in the ESI case before you formed your opinion, correct?

A. Not all of them, yes.

Q. All right. And you didn't read, for example, the depositions of the inventors before you formed your opinions, correct?

A. If it is not in here, then that is correct.

Q. Okay, fine. And you didn't read the transcript of the Markman hearing in ESI before you formed your opinion, correct?

A. I don't know, what is Markman?

Q. Okay.

A. No, but I really don't know what a Markman -- but if it is not here, then I must not have.

Q. Are you aware of the fact that the judge in the ESI case held a hearing to figure out what "coating material" means? Are you aware of that fact, sir?

A. It might have come into discussion, but not really.

Q. But you didn't read the transcript of that hearing, correct?

A. That is correct, yes.

Q. And you didn't read the transcript of the summary judgment hearing in the Upsher case before you formed your opinions, correct?

A. If it is not here, then you are right. That is correct.

Q. And you only skimmed the depositions of Dean Banker before you formed your opinions, correct?

A. Yes, I remember mentioning that I skimmed, yes.

Q. And now you list some other depositions in paragraph 3, Mr. Block, Mr. Robinson, Mr. Rhodes, Vickie O'Neill, Dr. Langer, correct?

A. Yes.

Q. Now, I take it in 20 hours you were only able to skim those depositions as well, fair?

A. The 20 hours was for the report. As I said, I -- I must have spent more hours in reading the material.

Q. Well, that's not what you testified in your deposition, is it?

A. Let's go to page 20.

Q. Yeah, look at page 18. What you testified to is you'd spent 20 hours on this matter prior to the time you wrote your report, correct?

A. Page 18, right?

Q. Yes, sir, beginning on about line 7.

A. The matter refers to the report.
Q. I see.
A. Yeah.
Q. Okay.
A. Oh, it is right here, sorry.
MR. NOLAN: Your Honor, just -- I think it's worthy of note since it was made an issue and I don't want to create any special new rule that that page that was just put up says that he was retained to provide rebuttal against Langer, is that true, and he said yes. So, I think that's pertinent to what we talked about earlier.
BY MR. LAVELLE:
Q. Would you go back to page 17 of your deposition, please?
A. Okay.
Q. Now, on page 17, you were asked the question -- and let's just sort of see if we understand your testimony.
"QUESTION: When were you retained," do you see that on line 8?
A. Yes.
Q. The date you want?
A. Yes.
Q. You answered, "Sometimes in September."

A. Yes.
Q. And you said that Ms. Sarris called you.
A. Yes.
Q. And then I asked you the question, "How much time between September and today have you spent working on matters in connection with this lawsuit?"
Do you see that question?
A. Yes.
Q. And you said approximately 30 hours, correct?
A. Sir, I cannot give you the exact number, but I billed for maybe 30 hours or so.
Q. Somewhere in that ballpark.
A. Yes.
Q. "QUESTION: Approximately 30 hours. Are you comfortable with that?
"ANSWER: Yes."
A. Yes, that is right.
Q. All right. So, your testimony back in November was that from the start of your engagement through the deposition, you'd spent 30 hours in total working for the FTC staff, correct? That's what you say.
A. Yeah, yeah.
Q. All right. And then on page 18, I asked you how much of that time was spent before you wrote your report.

A. Um-hum.
Q. And you said about 20 hours.
A. Yes.
Q. Correct?
A. Um-hum.
Q. So, your testimony back in November was that from the time you were retained until the time you finished your report, you'd given -- you'd spent 20 hours only working on this entire engagement, correct? That's what you said?
A. I think putting it into perspective, it is 20 hours for the report, and good estimate would be 30 to 50 hours.
Q. But that's not what you said, right? You said 20 hours before the report, 30 hours in total. That's what you testified to, correct?
A. Okay, yes, I...
Q. And was that testimony truthful at the time?
A. Yes.
Q. Okay.
A. That's all I billed. I might have had more, but I didn't bill more.
Q. I see. You didn't do any testing in forming your reports, correct?
A. I was not asked to.

Q. And you didn't do any, correct?
A. I didn't do any, and I didn't need to do it either.
Q. Okay. And you didn't do any lab work of any kind in forming your opinions, correct?
A. Again, I was not asked for that. I was not retained for doing experimental work. I was asked --
Q. And you didn't do any, correct?
A. I did not do it.
Q. And you haven't published any papers relating to potassium chloride tablets, have you, sir?
A. You asked me that question in my deposition, and I said there might be instances where potassium chloride might have been used in -- as a -- as a modeling compound, something of that sort, but not specifically sustained release potassium chloride, that is correct.
Q. Okay, fine. And you haven't published any original research on ethylcellulose as a coating material either, have you, sir?
A. You asked me the same question then, and I remember telling you that ethylcellulose is a very common component used, and it has -- I have worked with it for research purposes, so it might be in the publications, but I have not specifically concentrated

on EC.

Q. And you haven't published any original research relating to the use of HPC as a coating material either, have you, sir?

A. I think the answer was same for EC.

Q. No that you can recall, correct?

A. No, the same answer meaning that it might be part of research activities but not specifically on HPC.

Q. And you haven't published any original research related to sorbitan monooleate, correct?

A. Again, sorbitan monooleate, same as HPC and same as EC. These are very commonly used ingredients.

Q. And you haven't published any original research relating to polyethylene glycol either, correct, sir?

A. These are age old compounds, the same answer I gave at that time.

Q. Very good.

A. Um-hum.

Q. Would you turn to your CV, which is attached to Exhibit 750?

A. Yeah, um-hum. 750.

Q. And I want to ask you a question, under the section Universities Attended.

A. 1280, right? Which number?

Q. If you go to SPX 750, it is your report.
A. Yeah. And following that?
Q. Yes, and attached to that is your CV, sir.
A. Yes.
Q. And then on the second page, you have an entry, Universities Attended, correct?
A. That is correct.
Q. And you list Bombay University?
A. Um-hum.
Q. In India, that's where you got the equivalent of your Bachelor's Degree, right?
A. That is Bachelor's, not equivalent of, it is Bachelor's Degree. Sorry.
Q. It's a full four-year program. Is that right?
A. Yes. Six years, actually.
Q. Very good, a six-year program. And next you list Duquesne University where you got your Ph.D.?
A. That's correct.
Q. And how many years did you spend on that, sir?
A. Four years.
Q. Four years. On top of those two, you list the Massachusetts Institute of Technology, correct?
A. Yes.
Q. And you didn't get any degrees there, correct?
A. No. As I said, certification, it was

certification program.

Q. You went to a one-week program, right?

A. Yes, it was a one-week intensive program.

Q. All right. And the title of that program was Advances in Controlled Release Technology?

A. That is correct.

Q. And that is a program that MIT gives every summer, correct?

A. That is correct.

Q. And it's -- every summer, it's about advances in controlled release technology, correct?

A. It has to be put into the right perspective. It is advances in controlled release technology. It is not every year advances, but it is a consolidated program which talks about the kind of comprehensive understanding of the subject matter, if at all dependent on the instructor's perspective.

Q. And if you look in your book, for example, CX 1676 is this year's program. There's a summary of this year's program for Advances in Controlled Release Technology, correct?

A. Yeah, it says that. It is not here, but it says there, yeah.

JUDGE CHAPPELL: Sir, could you speak up, please?

THE WITNESS: Yes, it says here. It is not here in my book.

JUDGE CHAPPELL: Try moving the microphone closer.

THE WITNESS: Maybe I'll move --

JUDGE CHAPPELL: It will bend. Thank you.

THE WITNESS: Yes.

BY MR. LAVELLE:

Q. All right. Now, the professor at MIT who runs that program is Dr. Robert Langer, correct?

A. He coordinates the program. He is the organizer of the program.

Q. He's the program director.

A. That is his title. That's what it says.

Q. And that's the same Dr. Langer who testified in this case, correct?

A. That is correct.

Q. And you took his course in 1989. Is that right?

A. That is correct.

Q. And also on the faculty who helped teach you that intense week was Dr. Peppas, correct?

A. Yes, all these were there except Dr. Klibanov, so yes, Peppas was there.

Q. Very good, thank you, sir.

You've testified in four other cases in the last two or three years. Is that correct?

A. Yes.

Q. And each time it's been for a generic drug company, correct?

A. Yes.

Q. And on at least three of those occasions, you've offered the opinion that the patent in the case was invalid, correct?

A. Read that question again.

Q. Sure. On at least three -- I'll re-ask it.

In at least three of those four occasions, you testified that the patent in the lawsuit was invalid, correct?

A. Part of it was noninfringement and -- that is correct, yes.

Q. In at least three of those cases, you testified that the generic drug company didn't infringe the patent, correct?

A. That is correct, and we won in all these cases.

Q. And in one -- and in the fourth case, you weren't called upon to give any opinions with respect to validity or infringement, correct?

A. Yeah, that's the FTC case, yes.

Q. You testified in the FTC for Andrx, correct?

A. That is right.

Q. And you testified about dissolution testing, right?

A. That is correct.

Q. Now, as I understand it, sir, the first thing you did when you -- when the FTC staff hired you was to go through the '743 patent and its claims. Is that right?

A. That is part of it, yes.

Q. And next you looked at the Paragraph IV certifications that Upsher and ESI submitted, correct?

A. Upsher. I did not see ESI's.

Q. You looked at ESI's Paragraph IV certification?

A. No, I have not.

Q. You have looked at Upsher's.

A. Upsher's, yes.

Q. Okay, fine. And those Paragraph IV certifications, that's where Upsher stated its position as to why it felt it didn't infringe the '743 patent, correct?

A. Yes. Paragraph IV certification, for benefit of everyone, is the certification that we have -- generic companies have to provide to the FDA that they are not infringing any current active patent.

Q. Okay. And you reviewed those materials to form

your own view on what the merits of the case were, correct?

A. Yes.

Q. Okay. And after you formed your own views, at that point you went back and started looking at the underlying evidence in the Upsher and ESI cases, correct?

A. The sequence of the events were I reviewed the patent, then I looked at material, I looked at the -- both the generic contestants for that '743 patent, and then I went back and said, yes, this is what I can understand of the patent, and that's how it went.

Q. And you first set out to form your own independent view of the merits of the two cases, correct?

A. Yes, that is normally what I do.

Q. And after you did that, after you formed your own independent view, you went back to look at the underlying evidence in the Upsher and ESI cases, correct?

A. Additional evidence, yes.

Q. Okay, fine. Thank you, sir.

And what you're here to testify to today are your own opinions as to the merits of the Upsher and ESI cases, right?

A. Yes, I have my own opinion.

Q. And you made your own decisions about which facts are relevant and which facts aren't relevant to your opinion, correct?

A. That is correct, based on all the information that I have, yes.

Q. And if your opinions here today conflict with the evidence in one of the two cases, you're going to testify as to your opinions, correct?

MR. NOLAN: Objection, just that it's not clear what this question is asking for when it refers to his opinions and if the evidence was different. It's vague and unclear. It's a leading question, which is fine; it's just completely vague and incomprehensible.

JUDGE CHAPPELL: Overruled. See if he can answer it.

THE WITNESS: Please repeat the question.

JUDGE CHAPPELL: We can have Susanne read it back.

MR. LAVELLE: Would you please read it back for him?

(The record was read as follows:)

"QUESTION: And if your opinions here today conflict with the evidence in one of the two cases, you're going to testify as to your opinions, correct?"

THE WITNESS: I know my opinions are different than the one -- the opinions expressed by others, so there will be conflict, but I am -- as a -- I was rendered to provide a expert opinion on technical grounds, and that's what I'm going to provide. It may conflict, but that's what my opinion's going to be.

BY MR. LAVELLE:

Q. And in fact, in places your testimony does conflict with the evidence in the underlying cases, doesn't it?

MR. NOLAN: Objection, Your Honor. It's not clear that there was any evidence since there never was a trial. There are materials, documents and the like and reports, but typically we don't call expert reports evidence.

JUDGE CHAPPELL: He was -- overruled. The question was whether his testimony does conflict. Overruled.

Repeat the question, Susanne.

(The record was read as follows:)

"QUESTION: And in fact, in places your testimony does conflict with the evidence in the underlying cases, doesn't it?"

THE WITNESS: The way I understand the question is the information provided here through

experimentation, if that is called as evidence, or the reports that have been submitted by various experts, by -- from -- from Schering, those conflict with my opinion. So, if that is the evidence, then yes, my testimony will be conflicting -- will be in conflict with that, with those opinions.

BY MR. LAVELLE:

Q. Okay. Okay, let's talk about the Upsher case for a while.

A. Okay.

MR. LAVELLE: And Your Honor, I'm going to ask that while we're talking about the Upsher case that we go onto the confidential record.

JUDGE CHAPPELL: Okay, I am going to have to ask the public to leave the courtroom. We are going in in camera session. You will be notified when we go back in public session. Thank you.

(The in camera testimony continued in Volume 26, Part 2, Pages 6488 through 6530, then resumed as follows.)

JUDGE CHAPPELL: You may proceed.

MR. LAVELLE: Thank you, Your Honor.

BY MR. LAVELLE:

Q. Sir, once again, your testimony with regard to the ESI case is on the issue of infringement, correct?

A. Yes, I think so, I can accept that, yes.
Q. Okay. And let's take a look at SPX 2041 in your book. Let's see if we can't quickly see what we agree on here, okay?
A. Okay.
Q. We agree, don't we -- again, we are going to compare ESI's product to claim 1 in this claim chart, okay?
A. Yes.
Q. Now, we agree that ESI's product is a tablet of potassium chloride, correct?
A. Yes.
Q. And we agree that ESI's product has potassium chloride in the range specified by the claim, correct?
A. Yes, that is correct.
Q. And we agree that ESI's product has ethylcellulose in the range specified by the claim, correct?
A. Yes, that is correct.
Q. And we agree that ESI's product has HPC, one of the two things specified in the claim for the second chemical, right?
A. It does have HPC.
Q. All right. And we agree that it has HPC at approximately 1 percent by weight of the crystals,

which is within the range of the claim, right?

A. Yes, that is correct.

Q. And we agree that ESI uses Ethocel 100, which has a viscosity of greater than 40 centipoise, correct?

A. Yes, that is correct.

Q. And the issue that you question has to do with the term "coating material," correct?

A. In the general sense as well as we need to qualify that. The coating material, if you read the claim 1, it says a coating material for the individual potassium chloride crystals, the coating material comprising ethylcellulose in the amount of so and so based on a total weight of the coated crystals and at least one of the -- one member. So, it is a combination. That's where I take issue.

Q. Okay. And you -- you agree, don't you, that the word "mixture" doesn't appear anywhere in that claim?

A. It doesn't appear anywhere in the claim. It -- it does appear in the other parts of the patent .

Q. Okay. And it's the claim -- is it your understanding that it's the claim that's what defines whether or not there's infringement or not? Is that your nonlegal understanding of how patents work?

A. No.

Q. Okay.

A. My understanding is if the claim does not clearly state what is and what is not within that claim, whether it is a term or the numbers or the names of products or terms such as anything material as plasticization or something like that, then I have to look into the text of the entire patent in order to understand that and then connect it, because the claim as such cannot be treated in isolation.

Q. If the term "coating material" embraces two distinct layers, then ESI would infringe this claim, correct?

A. You are asking me to speculate?

Q. I am asking you to answer a hypothetical question. If -- I understand you don't agree with it, but if the term "coating material" were construed to cover two separate layers, one of EC and one of HPC, then ESI would infringe this claim, correct?

MR. NOLAN: Your Honor, it's calling for a legal conclusion, and Dr. Banakar is a scientist.

MR. LAVELLE: Your Honor, in fact, it's calling for a factual conclusion, and he's testified about this already on direct.

JUDGE CHAPPELL: I'll sustain it as a legal conclusion. I'll allow it as to his opinion based on

the opinions he's rendered here today.

BY MR. LAVELLE:

Q. Do you have the question in mind, sir?

A. Can you please read the question?

(The record was read as follows:)

"QUESTION: I am asking you to answer a hypothetical question. I understand you don't agree with it, but if the term 'coating material' were construed to cover two separate layers, one of EC and one of HPC, then ESI would infringe this claim, correct?"

THE WITNESS: If the claim construction specifically, explicitly mentions that, then yes.

BY MR. LAVELLE:

Q. Okay, fine. And you don't think "coating" is a word that can be used to have two layers, correct?

A. Process of coating is multilayer. So, if you are talking in the context of coating process, then it is a multilayer application. If you are talking about coating as a noun, that this coating was or that coating is, then it is a distinct layer.

Q. I see. And would you take a look at SPX 2042. This is The Dictionary of Pharmacy. You've seen this before?

A. The Dictionary of Pharmacy, yes.

Q. Yes. And the definition of "coating" from The Dictionary of Pharmacy is defined as covering a tablet with one or more than one protective layer, correct?

MR. NOLAN: Your Honor -- withdrawn. I was going to object to something, but I'll just let it go.

THE WITNESS: It says here, again, without specifying any details, it just -- just in general a definition.

BY MR. LAVELLE:

Q. And if you apply that definition of "coating" in claim 1, ESI infringes, correct?

MR. NOLAN: Your Honor, I object, because it refers to a "coating," and the questions before this have referred to a "coating material," a mischaracterization.

JUDGE CHAPPELL: If the witness doesn't understand the question, he can ask you to clarify it. Overruled.

THE WITNESS: Here "coating" is interpreted as a noun, which is covering a tablet which has these covers. It doesn't say anything about the composition or material or nothing. So, it is -- it is an inconclusive definition, but it does provide some understanding that, yes, something that covers the surface will be considered as coating.

BY MR. LAVELLE:

Q. And if something that covers the surface with two layers is how that claim 1 is construed, ESI would infringe it in your understanding, correct?

A. No.

Q. Why not?

A. Because here there is nothing to go there by. It doesn't say a coating layer, one of this and one of other. It just says one or two layers. It is just the process of coating, which happens anyway. You have -- you have to do it multilayer or else you will not get the right coating.

Q. I see. If the word "coating material" -- which is I take it what you get when you go through the coating process. Is that your understanding?

A. Can I hear the question back again, please? Sure.

(The record was read as follows:)

"QUESTION: If the word 'coating material' -- which is I take it what you get when you go through the coating process. Is that your understanding?"

THE WITNESS: No, "coating material" is what is the composition that we are going to coat as opposed to what we get after coating. So, that is the reverse actually of what you said.

BY MR. LAVELLE:

Q. All right. Are you telling -- is it your testimony that "coating" can be a process that has multiple layers but that the noun "coating" can only have one layer? Is that your testimony?

A. Yes, what I said is coating as a noun is a layer, which may have a composition A, then another coating have a composition B. The coating process is -- whether it is A or B, it goes through multiple layering, because that's how the process -- it is inherent to the process.

Q. Let's talk about mixing for one moment, okay, because it's getting late, but I do want to ask you one last thing about the mixing evidence that you talked to, and the one item that you identified for us is that figure 8d out of Dr. Langer's SEMs. Do you recall that?

A. Yes.

Q. And could we get a picture of 8d, please?

Now, this is the image that you believe shows some mixing. Is that correct?

A. No, this is the image which shows two different layers.

Q. I'm sorry, I'm sorry, I'm tired.

This is the image that you believe shows two

different layers, correct?

A. Yes.

Q. And you can't say whether or not there's some mixing of EC or HPC shown in this picture, correct?

A. With all the experimentation that -- that was done and that was relied on by Dr. Langer, this figure as well as 7d, I guess, shows me that there is a demarcation in the coatings, and that's what I -- even with no qualification as to what were the details of the experimentation, how did you decide on picking this versus any other, it does show the difference. That's what my contention is.

Q. Okay, and that's your contention, but you can't say whether or not there is some mixing present in that photograph, can you?

A. That's one reason why the SEMs are inconclusive, so here it shows the two layers supported by Hopfenberg's experiment showing the outermost layer, which is highly soluble, comes out very quickly, that putting together, yes, these are two distinct layers.

Q. Okay. And these SEM photographs were available in the original ESI litigation, correct?

A. To me they were available as xeroxed copies.

Q. Right, but they were available for the experts in the original ESI litigation, correct?

A. I don't know.
Q. Oh, okay.
A. I was not there at that time.
Q. Did you review the record? Did you review Dr. Hopfenberg's declarations from the ESI case?
A. I might have. I don't recall.
Q. Okay. And do you recall if you read Dr. Hopfenberg's deposition from the ESI case?
A. I have -- I have read that, but I don't recall the details, no.
Q. Okay. And do you recall if you read Dr. Butler's declaration from the ESI case?
A. William Butler?
Q. Yes.
A. Yeah, I -- if it was there, I read it. Again, don't ask me to recall, because I would not be able to.
Q. It's correct, isn't it, sir, that none of the experts in the ESI case felt that Figure 8d shows two layers, correct?
A. I can't recall that now.
Q. Okay. And it's correct, in fact, isn't it, that no one in the ESI case, none of the experts on either side found any evidence of mixing in Figure 8d, correct?
A. I don't know.

Q. Let me ask you one other question about your opinion. Is it your opinion that what I've just labeled A is the HPC layer or the predominantly HPC layer?

A. Yeah, the top part is most likely higher, because we do see something there which is getting destroyed.

Q. So to there maybe?

A. Yeah, that would cover all of it.

Q. And this would be the HPC layer in your mind?

A. Right.

Q. And what I'll now label B, this is what you would consider to be the EC layer in your --

A. Given all information that I have and based on what I read.

Q. Okay. And so the HPC layer would be about the same or slightly thicker than the EC layer. Is that your testimony?

A. No, that is not my testimony, because I don't know the thickness layer. There are other things -- SEMs become inconclusive, because what Dr. Langer -- excuse me, Dr. Mathiowitz did -- what Dr. Mathiowitz did was she took a razor blade and she cut those. So, you never know what angle it was cut, and then the scans were taken. So, I cannot say whether the layers

were the same thickness, but the demarcation is -- I think is pretty close. I can see it, yes.

Q. Okay, I guess maybe I didn't understand your answer.

Is it your testimony that the HPC layer is roughly the same thickness as the EC layer?

MR. NOLAN: Your -- Your Honor, I'm going to object in the sense that it's not clear from this diagram what layer he's referring to is the HPC layer, whether it's A or HPC on top of A. I know that earlier Dr. Banakar gave testimony referring to the inner core and so forth. So, I would like this, if possible, clarified as to what layer is it that Mr. Lavelle is referring to as the HPC layer when he asks this question.

JUDGE CHAPPELL: Dr. Banakar's an intelligent gentleman. If he needs a clarification, he'll ask for it. Overruled.

THE WITNESS: The question, please?

BY MR. LAVELLE:

Q. Let me rephrase it to be as clear as I can.

A. Okay.

Q. You told me that what I marked as letter A on this exhibit is the -- what you think is the HPC layer, correct?

A. Yes.

Q. And you told me that what I labeled B on this figure is the -- what you consider to be the EC layer, correct?

A. Yeah.

Q. And my question is, on -- looking at this Figure 8d that you rely on, the HPC layer is shown as -- as roughly the same size as the EC layer, correct?

A. And that I cannot say it. I cannot say that, because I gave you so many reasons for that.

Q. Okay.

Your Honor, could I have one second, please?

JUDGE CHAPPELL: Yes, you may.

(Counsel conferring.)

BY MR. LAVELLE:

Q. I want to go back to a question I asked you, because I think I misspoke. I'm fairly certain I misspoke.

I was asking you about the testimony of Dr. Hopfenberg and Dr. Butler and their expert reports and their depositions. Do you recall that?

A. Yes.

Q. And we were talking about the experts who were experts in the ESI case.

A. Yes.

Q. Okay. And the question I meant to ask you that I didn't is isn't it a fact that neither Dr. Hopfenberg nor Dr. Butler relied on Figure 8d as evidence of the existence of two separate and distinct layers in the ESI product?

A. That may be possible. I don't recall, but Hopfenberg had his own experiments, so he might have felt very strongly about that. So, I don't recall.

Q. Okay. And it's fair to say based on your review of the record that no expert other than you has seen evidence for separate layers in Figure 8d of the Dr. Langer test data, correct?

A. I don't know. I can't recall. I don't know.

MR. LAVELLE: Okay, Your Honor, I don't have anything further. Thank you.

JUDGE CHAPPELL: Any cross from Upsher-Smith?

MR. CURRAN: Yes, it's very brief, Your Honor. It does require us to go briefly into in camera.

JUDGE CHAPPELL: Then we shall. I must ask the public to leave the courtroom once again. We're going into in camera session.

(The in camera testimony continued in Volume 26, Part 2, Pages 6531 through 6534, then resumed as follows.)

JUDGE CHAPPELL: You may proceed.

MR. NOLAN: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MR. NOLAN:

Q. Dr. Banakar, does the '743 patent ever use the word "plasticizer"?

A. No, it does not.

Q. You've reviewed the prosecution history, correct?

A. That is correct.

Q. Did the examiner from the U.S. Patent and Trademark Office ever use the word "plasticizer" in his comments?

A. No, he did not.

Q. Did the Schering attorney, Mr. Maitner, ever use the word "plasticizer" in his responses to the patent examiner?

A. No, he did not.

Q. Did the Upsher-Smith experts in the original matter believe that this patent related to use of a plasticizer?

A. The way I understand it, they were specifically looking at going outside the claims, which is not to use 40 or higher viscosity grade ethylcellulose.

Q. With respect to plasticization of

ethylcellulose, did Dr. Rhodes take an opinion of whether there was -- whether or not -- let me rephrase the question.

Did Dr. Rhodes -- was Dr. Rhodes an expert, a technical expert, for Upsher-Smith?

A. Yes, he was, I recall that.

Q. And did he -- what was his position on whether the '743 patent relates to use of a plasticizer or not?

MR. CURRAN: Objection, Your Honor. If this is calling for in camera material, I request that we go in camera.

MR. NOLAN: I don't think, Your Honor, it does relate to in camera material. It simply relates to the concept of whether this patent has anything at all to do with plasticization.

MR. CURRAN: Your Honor, I'm comfortable staying in -- on the public record as long as the witness understands that he is not to reveal anything about Upsher-Smith's proprietary formulation in his response.

JUDGE CHAPPELL: Do you want to voir dire this witness, Mr. Curran, and make sure he understands?

MR. CURRAN: That's fine, Your Honor, thank you.

VOIR DIRE EXAMINATION

BY MR. CURRAN:

Q. Dr. Banakar, you're aware that some of the questions you're being asked today relate to trade secrets of Upsher-Smith?

A. Yes.

Q. All right, and that those trade secrets relate to its formulation?

A. Yes.

Q. Formulation relating to its M20 product?

A. Yes.

Q. Are you aware that at the moment we are in a public session?

A. Yes.

Q. Are you aware that we have the ability in this proceeding to move into an in camera session?

A. Yes.

Q. And are you aware of my request that while we're in the public session, you do not reveal any information about Upsher-Smith's proprietary formulation?

A. Yes, I will make sure of it.

Q. And are you aware that you have the ability to alert the Judge when you believe a question calls for the revelation of Upsher-Smith's proprietary information?

A. Oh, I didn't know that, but now I can, I guess. I would -- I would -- yes, sorry about that. I didn't know that. Okay, sure.

Q. And do you undertake not to reveal Upsher-Smith's proprietary formulation --

A. Yes.

Q. -- while we're on the public record?

A. Yes.

MR. CURRAN: Thank you, Your Honor.

MR. LAVELLE: Your Honor, can I have one second?

(Counsel conferring.)

BY MR. CURRAN:

Q. Sir, do you understand that the question you've just been asked by Mr. Nolan relates only to the face of the patent itself, not to Upsher-Smith's proprietary formulation?

A. Yes, the patent as such, nothing related to any specific formulation.

MR. CURRAN: Thank you, Your Honor.

JUDGE CHAPPELL: Okay, Mr. Nolan, do we need the court reporter to read the question back?

MR. NOLAN: Your Honor, if I could just ask the question again.

JUDGE CHAPPELL: Okay.

REDIRECT EXAMINATION (cont)

BY MR. NOLAN:

Q. You understand I'm referring specifically to the patent and the opinions of Upsher-Smith's experts about what that patent related to, okay?

A. Yes.

Q. Okay. We've just progressed from the patent, the patent examiner's view, and the -- the -- Schering's attorney, whether any of them have referred to the use of plasticizer, and I take it your answer so far has been no.

A. That is correct.

Q. Now, with respect to the Upsher-Smith experts in the original litigation, is it also correct that they didn't think the '743 patent had anything to do with use of a plasticizer?

A. That is correct. That is correct, yes.

Q. Um-hum. Have you ever heard anyone except Dr. Banker say that the '743 patent has something to do with the use of a plasticizer?

A. No, as a matter of fact, actually before the -- before the interruption, you had asked me what did Dr. Rhodes talk about. In his report, he really goes to the extent of stating on the record that this whole theory of plasticization is a conjecture of Dr. Banker.

So, this is a catch-all thing that was kind of connecting to show that, yes, this -- there is some similarity.

Q. Um-hum. So, if the '743 patent has absolutely nothing to do with use of a plasticizer, does it matter whether anything else -- I think at this point we should -- I'll hold the question for a second. We should go into confidential session.

JUDGE CHAPPELL: At this time I'll need to ask the public to leave the courtroom, please. You will be notified when the in camera session is over.

(The in camera testimony continued in Volume 26, Part 2, Pages 6535 through 6542, then resumed as follows.)

RECROSS EXAMINATION

BY MR. CURRAN:

Q. Dr. Banakar, Mr. Nolan a moment ago asked you about some of the other cases in which you testified. Sir, one of those cases was Biovail versus Andrx, correct?

A. That is correct.

Q. And you testified for Andrx in that case?

A. That is correct.

Q. Another one of those cases was Glaxo versus Andrx, correct?

A. Yes.
Q. And you testified for Andrx in that case?
A. For deposition. That -- now, we won that case on summary judgment.
Q. Right, but you were retained by Andrx in that case as well, correct?
A. Correct, yes.
Q. And a third case in which you testified was Astra versus Andrx, correct?
A. That is ongoing, yes.
Q. All right. And in that case as well, you were retained by Andrx, correct?
A. Yes.
Q. And sir, you're aware that Andrx is a major competitor of Upsher-Smith?
A. It is a generic company, so all generic companies are competitors of each other, so --
Q. Are you --
A. -- yeah, I guess so.
Q. Are you aware that Mr. Rosenthal of Andrx was a witness for complaint counsel in this case?
A. No, I was not aware.
MR. CURRAN: Nothing further, Your Honor.
MR. NOLAN: Your Honor, I have one question, and it does call for --

JUDGE CHAPPELL: But is your question within the scope of the recross?

MR. NOLAN: Yes.

JUDGE CHAPPELL: I'm going to have to ask the public to leave the courtroom once again. We're going into in camera session.

(The in camera testimony continued in Volume 26, Part 2, Pages 6543 through 6544, then resumed as follows.)

JUDGE CHAPPELL: If they turn my in camera sign, they get their name on the record.

Any more questions for this witness?

MR. LAVELLE: No, Your Honor.

MR. NOLAN: No, Your Honor.

MR. CURRAN: No, Your Honor.

JUDGE CHAPPELL: Thank you, Dr. Banakar. You're excused.

THE WITNESS: Thank you very much.

JUDGE CHAPPELL: Anything else tonight?

MR. NIELDS: Not from us, Your Honor.

MR. CURRAN: Dr. Kerr can wait until tomorrow, Your Honor.

JUDGE CHAPPELL: Okay. Since it is past 7:00 we will start tomorrow one hour late, so we will adjourn until 10:30 tomorrow morning.

(Whereupon, at 7:20 p.m., the hearing was adjourned.)

C E R T I F I C A T I O N O F R E P O R T E R

DOCKET/FILE NUMBER: 9297

CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

DATE: MARCH 5, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 3/6/03

SUSANNE BERGLING, RMR

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE